EFFECTIVENESS OF NATURAL HONEY APPLICATION ON ORAL MUCOSITIS AMONG PATIENTS UNDERGOING RADIATION THERAPY WITH OR WITHOUT CHEMOTHERAPY

DISSERTATION SUBMITTED TO
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY, CHENNAI
IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE
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MEDICAL SURGICAL NURSING
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CERTIFICATE

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G.JASMIN JOY

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ABSTRACT

A study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without Chemotherapy in selected hospital , kanyakumari district.

Quasi experimental, pre-test post-test control group design was adopted for this study. purposive sampling technique was used to select the samples. Out of 60 samples, 30 samples were in study group and 30 samples were in the control group.

The WHO Oral Mucositis Grading Scale was used to screen the oral mucositis in study and control group. Pre assessment was done on first day and post assessment was done on seventh day .

The findings reveals that, in study group during pre assessment, among 30 samples. The demographic variables in control group 10(33.33%) of them belongs to the age group between 51-60 years,16(53.33%) of them were males, 18(60%)of them were belongs to rural areas , 16 (53.33%) of them were Hindu religion, Marital status 30(100%)were married,14(46.67%) were primary education ,11(36.67%) were self worker, 30 (100%) were non -vegetarian 13(43.33%) had 13-24 months duration of illness,13(43.33%)belongs to 0-2 times of exposure to radiation therapy,5(16.67%) had undergone the 6-8 times of exposure to radiation therapy. During pre assessment, in study group ,26(87%) had moderate oral mucositis and 4(13.33%) had severe oral mucositis. In control group, 27(90%) had moderate oral mucositis, 3(10%) had severe oral mucositis. There was no significant difference in the pre assessment and post assessment level of oral mucositis in study and control group at 0.05 significant. There was a significant difference between the post assessment level of oral mucositis in study group and control group .

The study represents the natural honey application is efficient with the ‘t’ value level of 2.36 at 0.05 significant . Hence the researcher concluded as per the study that, oral mucositis can be reduced by natural honey application . This study statistically proved the natural honey application is effective on oral mucositis among patient undergoing radiation therapy with or without chemotherapy.

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CHAPTER I

INTRODUCTION

Health is a source of joy for everyday life. The mode of being healthy includes as defined by the **World Health Organisation**, a state of complete physical, mental, social wellbeing and not merely an absence of disease or infirmity.

A disease is a particular abnormal condition, a disorder of a structure or function, that affects part or all of an organism. Disease is often construed as a medical condition associated with specific symptoms and signs. It may be caused by factors originally from an external source, such as infectious disease, or it may be caused by internal dysfunctions, such as autoimmune diseases.

Cancer is a disease process that begins when abnormal cells is transferred by genetic mutation by cellular De-oxyribo Nucleic Acid. Cancer is one of the second largest killer disease next to heart disease. The chances of surviving the disease vary greatly by the type and location of the cancer and the extent of disease at the start of treatment. Cancer can affect people of all ages, and a few types of cancer are more common in children, the risk of developing cancer generally increases with age. In 2007, cancer caused about 13% of all human deaths worldwide (7.9 million). Rates are rising as more people live to an old age and as mass lifestyle changes occur in the developing world.**(Akush 2008)**

A prospective observational study was conducted to examine the burden of mucositis and risk of complications in head and neck cancer patients undergoing radiation with or without chemotherapy. Data was collected at every weeks and results showed that oral mucositis was initially developed in people with radiation therapy and severe mucositis and throat soreness occurred in 76 percent of patients (**Bjarnason, G.,2005**).

Cancers are a large family of diseases that involve abnormal cell growth with the potential to invade or spread to other parts of the body. They form a subset of neoplasms. A neoplasm or tumour is a group of cells that have undergone un regulated growth, and will often form a mass or lump, but may be distributed diffusely.

Oral cancer or mouth cancer, a type of head and neck cancer, is any cancerous tissue growth located in the oral cavity. It may arise as a primary lesion originating in any of the tissues in the mouth, by metastasis from a distant site of origin, or by extension from a neighbouring anatomic structure, such as the nasal cavity.

Many treatment options for cancer as with the primary including surgery, chemotherapy, radiation therapy, hormonal therapy, targeted therapy and palliative care. The treatments depends upon the type, location, and grade of the cancer as well as the person's health and wishes. The treatment intent may be curative or not curative.

Radiation therapy involves the use of ionizing radiation in an attempt to either cure or improve the symptoms of cancer. It works by damaging the DNA of cancerous tissue leading to cellular death. To spare normal tissues such as skin or organs, which radiation must pass through to treat the tumour, shaped radiation beams are aimed from several angles of exposure to intersect at the tumour, providing a much larger absorbed dose there than in the surrounding, healthy tissue. As with radiation therapy, different cancers respond differently to radiation therapy.

Chemotherapy is the use of drugs to kill cancer cells. However, when most people use the word chemotherapy they are referring specifically to drug treatments for cancer that destroy cancer cells by stopping their ability to grow and divide. These powerful medications circulate in the bloodstream and directly damage the cells that are actively growing. Because cancer cells generally grow and divide faster than normal cells, they are more susceptible to the action of these drugs. However, damage to healthy cells is unavoidable, and this damage accounts for the side effects linked to these drugs.

The combination of chemotherapy and radiation therapy given at the same time is sometimes called chemoradiation or radiochemotherapy. For some types of cancer, the combination of chemotherapy and radiation therapy may kill more cancer cells, but it can also cause more side effects.

Side effects of radiochemotherapy includes fatigue, nausea, vomiting, damage to the epithelial surfaces, intestinal discomfort, Infertility, mouth sores, throat sores

and stomach sores . As part of the general inflammation that occurs, swelling of soft tissues may cause problems during radiation therapy

Radiation therapy that is delivered to the head and neck area may cause mucositis. Mucositis is inflammation of the lining of the mouth and throat, called the mucus membranes. When radiation is administered directly to or near the head and neck region, chest, abdomen, or anal-rectal regions, it may cause damage to the mucosal lining of the entire gastrointestinal tract. This results in inflammation and sloughing of the mucosal cells, causing pain and increasing the risk of infection.

Patients who have a sore mouth or gums need to take special care of their teeth, as they are a primary site for infection and pain. These patients may need to utilize frequent oral hygienic measures and antiseptic mouthwashes. In addition, some patients find it helpful to rinse the mouth with water frequently in order to remove food and bacteria and promote healing.

Murray (2008) reported that, honey has been used remedy for hundreds of ills including as a gargle and as topical treatment for sores, mucositis and wounds .Honey is naturaly composed of sugar (about 76%)water (18%)and other ingredients like enzymes ,minerals and vitamins that make up about 6% espesically the glucose oxidase enzyme and vitamin c were found in honey, which may help to reduce the inflammatory changes in the mucosa. Honey is naturally high in sugar ,acid and is an antioxidant .Using honey in a mucositis will lessening the mucositis and help to remove the dead or damaged tissue to improve the healthy tissue and moist the mucositis environment. Modern research also support for this use in statistical findings and in isolation of antimicrobial and antifungal compounds. It is also to induce sleep, cure diarrhoea and treat asthma.

Background of the study.

The global burden of cancer continues to increase largely because of the aging and growth of the world population alongside increasing adoption of cancer causing behaviours particularly in smoking. (**Cline, 2011**)

The annual report of **World Health Organization (2014)** provides the estimated numbers of new cancer cases and deaths in 2014, as well as current cancer incidence, mortality, and survival statistics and information on cancer symptoms, risk

factors, early detection, and treatment. In 2014, there will be an estimated 1,665,540 new cancer cases diagnosed and 585,720 cancer deaths in the United States. Cancer remains the second most common cause of death in the United States, accounting for nearly 1 of every 4 deaths.

Martin (2012) reported that the Mucositis or oral mucositis is a typical radiation therapy-induced debilitating problem to such an extent that about 10% of the patients undergoing adjuvant radiation therapy, 40% of the patients undergoing neo adjuvant radiation therapy, and 80% of the patients being treated with stem cells suffer from this problem. Mucositis-induced pain disturbs patients and makes it difficult to eat and drink, resulting in indigestion and dehydration. Mucositis can also disturb speaking and communication with others, resulting in psychological and social problems. In addition, mucositis is accompanied by a wide range of oral mucosa alterations such as infection and bleeding, which could result in systemic infection.

Every year about 8,00,000 new cancer patients get registered with the **National Cancer Registry Programme in India** shows that, cancer is one of the major health problems in India at present . Lung and oral cancer are the most common types of cancer among men .whereas cervical and breast cancer among women in India .then were 5,56,400 cancer related deaths in India .In the year 2010, Out of which 71% of cancer patients (3,95,400) were of the age group between 30-69years .

In the rural areas, oral cancer still remains high and much a head of breast cancer. For instance, in Dindugal ,a rural centre, the incidence of oral cancer is at 25.9tailed by breast in a 2009-10 observation ,whereas Coimbatore, an urban centre, reflects the breast cancer is 20.3 and cervical cancer is 13.7. **V. Shanta, chairman, Adyar Cancer Institute, Chennai.** stated that tobacco use is the cause of about 22% of cancer deaths. Another 10% is due to obesity, a poor diet, lack of physical activity and drinking alcohol. Other factors include certain infections, exposure to ionizing radiation, and environmental pollutants. In the developing world nearly 20% of cancers are due to infections such as hepatitis B, hepatitis C and human papilloma virus. These factors, at least partly, by changing the genes of a cell. Typically many such genetic changes are required before cancer develops. Approximately 5-10% of cancers are due to genetic defects inherited from person’s parents and mainly focusing

about education, when girls study more; they are more likely to have better genital hygiene. It is the same with chewing tobacco.

A health treatment that is not classified as standard western medical practice is referred to as “alternative”. It encompasses a variety of disciplines that include everything from diet and exercise to mental conditioning and life style changes.

Significance and need for the study

Wan J et al., (2014) conducted an experimental study to validate the safety of and explore the effect of natural honey on oral mucositis, quality of life in hospitalized patients in School of Nursing, Hungkuang University, Taiwan. The finding shows that there was no significant changes in quality of life were reported by the control group . But the experimental group showed a significant improvement in the mucositis and facial mobility ($p<.05$) domains of quality of life.

Kavitha.,(2014) conducted a descriptive study to assess the side effects of radiation therapy in Chennai. Objectives were to assess the side effects of radiation therapy among patients undergoing radiation therapy and to associate the selected demographic variables with the side effects of radiationtherapy. There was a significant association between sex and mucositis at 0.046 with number of exposure to radiation therapy and pain level at 0.046.

Ronald.,(2010). Oral mucositis is a common and significant problem of cancer radiation therapy, especially patients who receives high-dose therapy. Two recently published retrospective analyses of patient complaints following radiation therapy have identified oral mucositis as the worst toxicity reported by patients, and what is more important is that patients indicated that oncology healthcare team members do a poor job of managing and providing methods of symptom relief. Twenty percent of patients surveyed indicated they received no symptom relief at all.

Reasons for increasing rates among younger age groups are combining knowledge about risk factors and available etiological data through increases in incidence at younger ages do not result in a number of cases were diagnosed given that such a large attributable risk is associated with tobacco and alcohol, however,

these increases may be preventable part of cancer treatment to control or kill malignant cells

During our educational visit, the researcher went to C.S.I Medical Mission Hospital, Neyyoor. On observation visit, the researcher had seen so many cancer patients undergoing radiation therapy with or without chemotherapy. They verbalize about the oral complaints about the oral mucositis and their sufferings. The researcher experienced during visit that, patients were hesitated to use with strong antiseptic solutions because of its burning sensation, with inspiration the researcher wanted to evaluate the effect on oral mucositis among patients who is undergoing radiation with or without chemotherapy. So the researcher selected this study with interest to reduce the oral mucositis through natural honey application.

STATEMENT OF THE PROBLEM

A study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital, Kanyakumari district.

OBJECTIVES

1. To assess and compare the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group and control group.
2. To evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group and control group.
3. To associate the post interventional level of oral mucositis among patients in study and control group with selected demographic variables in study and control group.

Hypotheses

H_1: There is a significant difference between the pre and post assessment level of oral mucositis among patients undergoing radiation therapy in study and control group.

$H_{2:}$ There is a significant difference between the post assessment level of oral mucositis among patients undergoing radiation therapy in study and control group.

$H_{3:}$ There is a significant association between the post assessment level of oral mucositis with the selected demographic variable.

OPERATIONAL DEFINITIONS:

Evaluate:

It refers to identify the difference between pre assessment and post assessment level to oral mucositis among patients undergoing radiation therapy with or without chemotherapy.

Effectiveness:

It is the desired changes brought out by the natural honey application on oral mucositis and is measured in terms of significant reduction in the post assessment score

Oral mucositis:

It is an inflammation of the mucous membrane of oral cavity as measured by WHO oral mucositis grading scale .

Natural honey application:

It is a sweet food made by bees using nectar from flowers which is stored in the nest,that has been extracted by the machine and preserved for storage. This honey is measured by ounce glass 10m.l used for applying in oral mucositis.

Radiation therapy:

It is the administering doses of radiation to treat cancerous growths in patients.

Chemotherapy:

It is the drug which is indicated to the cancer patients to kill the cancer cells and includes the patients those who had undergone the radiation therapy and chemo therapy at the same time.

ASSUMPTION:

1. Natural honey may improve the oral mucositis among patient undergoing radiation therapy with or without chemotherapy.
2. Patient undergoing radiation therapy with or without chemotherapy may have increased level of oral mucositis.

DELIMITATION:

The study is delimited with four weeks of data collection and unconsciousness of patients.

PROJECTED OUTCOME:

The finding of the study will help the patients undergoing radiation to reduce the impact of oral mucositis .

At the end of the study the patients undergoing radiation therapy with or without chemo therapy will understand and practice natural honey to reduce the level of oral mucositis

CONCEPTUAL FRAME WORK:

WIDENBACH'S PRESCRIPTIVE HELPING ART OF CLINICAL NURSING THEORY (1964)

Conceptualization refers to the process of developing and refining abstract. A conceptual model provide for logical thinking, for systematic observations and interpreting the observed data **(kozier,2009)**

The framework of this study based on "**Widenbach's Prescriptive Helping Art of Clinical Nursing Theory (1964)**" .the investigator adopted the model linked together in nursing practice. Nursing practice consist of identifying a patient's need for help, ministering the needed help and validating that, the needed help was met.

Phase1 -Identification:

According to this theory, "identification refers as an individual with unique experiences and understanding the patients perception". In the present study identification consist of identify the need through, the assessing the demographic variables and level of oral mucositis measure based on WHO oral mucositis grading scale.

Phase2 -Ministration:

According to this theory, "Ministration refers to provision of needed help". In this study ministration refers to natural honey application to oral mucositis in the study group to reduce the level of oral mucositis.

Agent – The researcher

Recipient- Patients undergoing radiation therapy with or without chemotherapy

Goal – To reduce the level of oral mucositis

Framework – C.S.I Medical Mission, International Cancer Center Neyyoor

Means - Natural honey

Phase3 -Validation:

According to this theory, “validation refers to patient’s needs have been met and that his functional ability has been restored as a direct result of the nurse’s actions”. In this step involves the assessment of level of oral mucositis. Level of mucositis is categorized as no changes, mild, moderate, severe and life threatening. Two possible outcomes are improving the level of oral mucositis in the study group and not reducing the oral mucositis of control group.

Feedback:

The level of oral mucositis had good progress in patients undergoing radiation therapy with or without chemotherapy after giving natural honey in study group. There was moderate and severe progress in level of oral mucositis in control group. At the end of the study, the researcher explained about the effectiveness of natural honey to the study and control group.

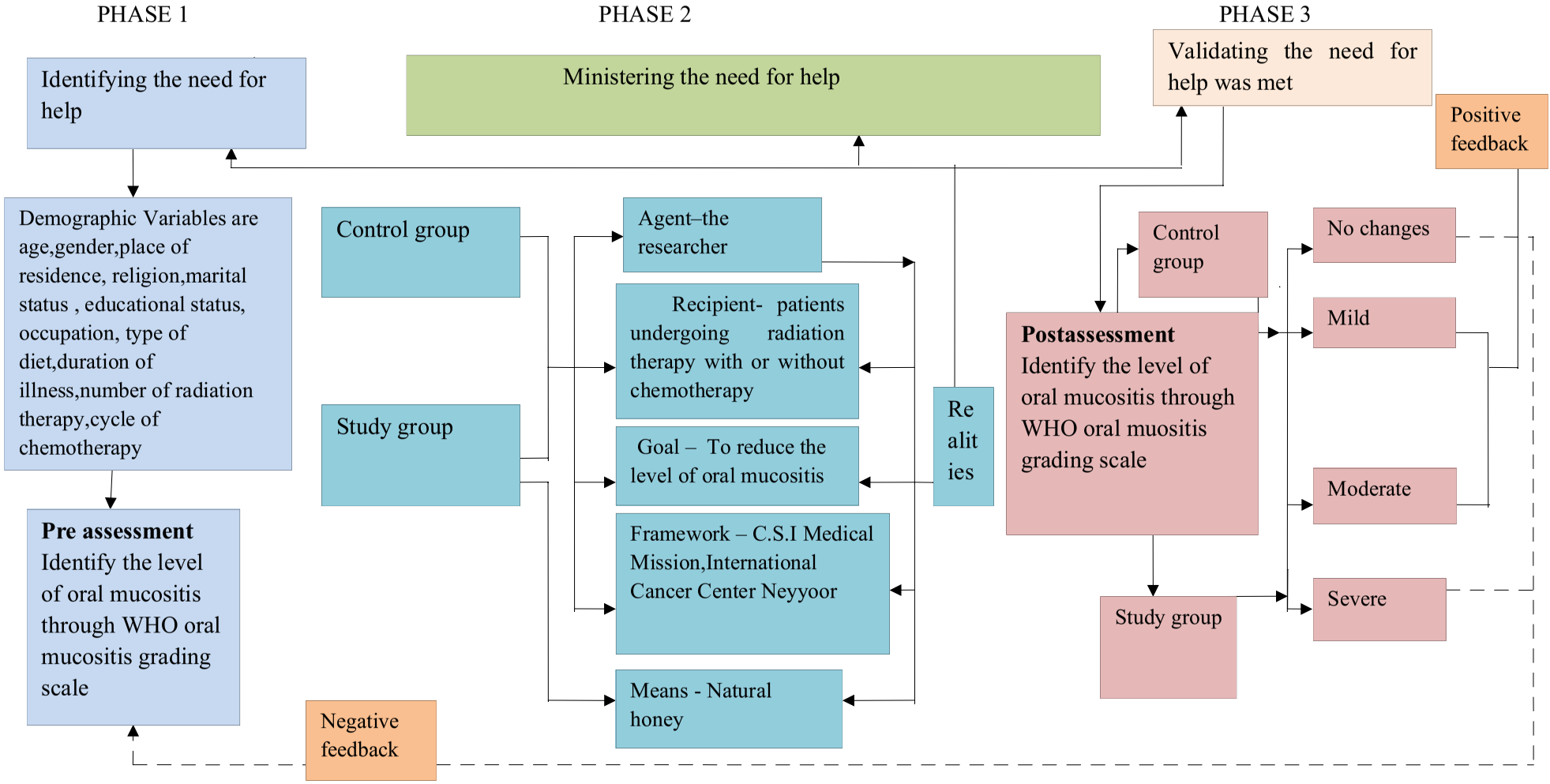

Fig :1 Conceptual Framework based on Modified Widenbach's Prescriptive Helping Art Of Clinical Nursing Model

CHAPTER II

REVIEW OF LITERATURE

Review of literature is a vital component of the research process. It gives the researcher orientation to the conduction of the study. It provides the source of research ideas for the new researcher.

The review of literature is presented under the following sub headings. Review of literature is related to

1. Studies related to cancer.
2. Studies related to oral mucositis.
3. Studies related to the honey.
4. Studies related to the effects of other therapies

Studies related to cancer:

Julienne. E, et al., (2014) conducted a longitudinal study to assess the cancer-related oral mucositis mechanisms, risk factors, and treatments among cancer patients in Brazil. 218 samples were chosen by purposive sampling technique. A structured questionnaire was used to score the cancer-related oral mucositis. 66% of the participants had affected the oral mucositis. The study concluded that there was high prevalence of cancer-related oral mucositis among cancer patients.

Arunachalam. D,et al., (2011)had performed a study on "quality of life in cancer patients with disfigurement due to cancer and its treatments. The aim of this study was to evaluate the effect of disfigurement due to cancer and its treatments on quality of life in Canada. A total number of 120 patients from the inpatient or outpatient department of oncology who had undergone various forms of treatment for cancer were included in this study. The study concluded that a sudden change either due to cancer or its treatment or due to side effects leads to significant social maladjustment and poor quality of life among cancer survivors.

Studies related to oral mucositis

Verdi. C.,(2005). Conducted a study to find out the incidence of oral mucositis in cancer treatment. Patients undergoing radiation therapy and chemotherapy were included in the study. Patients oral cavity was assessed weekly and identified that patients who undergoing chemotherapy oral mucositis usually develop oral mucositis from 10 to 12 days of administration and in radiation therapy mucositis occurred after 7 to 10 days of administration, the study findings that the incidence and severity was high in patients undergoing radiation therapy and chemotherapy

Bjarnason, G.,(2005).conducted a prospective observational study was conducted to examine the burden of mucositis and risk of complications in head and neck cancer patients undergoing radiation with or without chemotherapy . Oral mucositis was assessed two, four and six weeks by using questionnaire for head and neck cancer patients with a sample of 60. A 12 team instrument was used to measuring mouth and throat soreness and pain and limitation in oral functions. Data was collected at every weeks and results showed that oral mucositis was initially developed with radiation therapy and severe mucositis and throat soreness occurred in 76 percent of patients.

Fayed, L.,(2004)conducted an explored the relationship between oral mucositis and selected clinical and economic outcomes of patients with radiation and chemotherapy. Subjects who were participated in this study consisted of 92 patients from eight centers. Oral mucositis scoring system (Oral Mucositis Assessment Scale) was used to assess oral mucositis and examined the relationship between patients peak oral mucositis scores and days with fever, the occurrence of infection, days of Total Parenteral Nutrition (TPN), and days of injectable narcotic therapy, days in hospital, total hospital charges for the index admission, and vital status at 100 days. Results showed that Patients' peak oral mucositis scores reached the full range of possible values (0 to 5) and were significantly ($P<0.05$) correlated with all of the outcomes and it revealed that oral mucositis is associated with significantly worse clinical and economic outcomes in cancer treatment .

Studies related to honey:

Jabber.,(2013) conducted a study to analysed chemical components of 13 Saudi honey samples were identified according to anti-ulcer and antioxidant activity by using phytochemical and chromatographic analyses. The anti-ulcer activities were also evaluated, showing that oral administration of the honey samples reduced the intensity of ulcer scores when compared to the control group. Similarly, there was a highly significant reduction in the values of the ulcer indices and areas in rats that received the same sample ($P < 0.05$ and $P < 0.01$) in comparison with those of the ulcer control rats. Finally, the antioxidant activity of the honey samples was evaluated, revealing a proportional relationship between the anti-oxidant and anti-ulcer activities. The results of this study could be reached that the effectiveness of honey as an anti-ulcer increase with the increasing its antioxidant activities.

Sedhigai et al.,(2008) performed the Topical Application of Pure Natural Honey in Prevention of Chemotherapy Induced Oral Mucositis in Iran. **:** In this randomized clinical trial 48 patients with acute leukemia requiring chemotherapy were assigned to three equal groups. During induction or reinduction period of chemotherapy, first group received honey plus normal saline; the second one received just normal saline and third, (in control group) did not receive any prophylaxis. Patients were evaluated weekly for progression of mucositis according to the WHO mucositis scale. Data were analyzed with the Pearson Chi-Square and Fisher Exact test, by fifteen edition of SPSS software. In group of 'honey plus normal saline' no patients developed mucositis, while in normal saline group 4 patients and in control group 12 patients developed mucositis. The rate of mucositis was significantly lower in both intervention groups compared to control ($P < 0.001$).

Bradey et al.,(2008) conducted a systematic reviewed of honey uses and its potential value within oncology care. The inclusion and exclusion criteria were agreed by two reviewers. In total, 43 studies were included in the systematic review, which included studies in relation to wounds ($n = 19$), burns ($n = 11$), skin ($n = 3$), cancer ($n = 5$) and others ($n = 5$). In addition, a systematic review regarding honey use in wound care was also included. While the majority of studies noted the efficacy of honey in clinical use, five studies found honey to be equally as effective as the comparator and three found honey to be less effective than the comparator treatment.

Other research did not illustrate any significant difference between standard treatment regimes vs. honey treatment. Studies were generally poor in quality because of small sample sizes, lack of randomisation and absence of blinding. Honey was found to be a suitable alternative for wound healing, burns and various skin conditions and to potentially have a role within cancer care.

Gezawy.,(2006) conducted a study to find out the honey as topical prophylaxis against radiation therapy induced mucositis in head and neck cancer in Assiut university hospital Egypt . 40 patients diagnosed with head and neck cancer were entered in trial .enrolled patients were randomized to either the treatment group, undergoing concomitant chemotherapy and radiation therapy plus prior topical application without honey. Patients were evaluated clinically every week to assess the development of radiation mucositis. aerobic cultures and candida colonization assessment were undertaken, via oral and oropharyngeal swabs , prior to and at the completion of irradiation, and when infection was evident. In the result in treatment group, no patients developed grade 4 mucositis and only 3 patients (15%) developed grade 3 mucositis where as in the control group ,13 patients (65%)developed grade 3 to4 mucositis($p<0.05$). as the conclusion this study shows that prophylactic use of pure honey was effective in reducing mucositis resulting from radiotherapy in patients with head and neck cancer.

Studies related to effectiveness of honey and other therapies.

Wan J et al., (2014) conducted an experimental study to validate the safety of and explore the effect of natural honey on oral mucositis, quality of life in hospitalized radiation therapy patients in School of Nursing, Hung kuang University, Taiwan. A total of fifty-one subjects were in the study group where as fourty one subjects were in the experimental group were chosen by purposive sampling. The natural honey 20m.l was given for 14 days. A structured questionnaire, oral mucositis Scale was used to assess the oral mucositis and quality of life. Data were processed by SPSS 18.0 for Windows. The major statistical procedures applied were frequencies and percentages, independent t test, paired t-test, chi-square test, and repeated-measures ANOVA. A value of $P < 0.05$ was considered statistically significant. The finding shows that there was no significant changes in quality of life were reported by

the study group. But the experimental group showed a significant improvement in the mucositis and facial mobility ($p<.05$) domains of quality of life.

Cheng, K.F.,(2013)had conducted a prospective randomized cross over study was conducted to assess the effectiveness of two oral care protocols differing in the type of mouthwashes. The usages for this study were normal saline versus honey. Fourty patients undergoing radiation therapy were allocated to receive normal saline first and then honey. Subjects were evaluated in intervals of 3 to 4 days by using WHO grading for mucositis and 10cm visual analogue scale for oral symptom evaluation. The results showed that a significant difference in mean area of oral mucositis grade for subjects received normal saline compared to those received honey and revealed that normal saline may be helpful in palliating mucositis symptoms in radiation therapy

Indian Journal of Palliative Care., (2012) conducted a study to evaluate the effectiveness of topical application of natural honey and benzydamine hydrochloride in the management of radiation mucositis. The sample size comprised of 60 patients, of both genders, diagnosed with oral malignancy clinically and histopathologically and planned for radiotherapy. The patients were assigned into three groups by random sampling. Each group consisted of 20 patients. Group 1 patients were instructed for topical application of natural honey, groups 11 and Group 111 were instructed for topical application of 0.15% benzydamine hydrochloride and 0.9% normal saline respectively. The onset of mucositis and the severity of mucositis were graded during the course of the radiotherapy and two weeks after radiotherapy, with WHO mucositis grading in all the three groups. Pure natural honey can be an effective agent in managing radiation induced oral mucositis.

Farrington, M.,(2010) performed a randomized double blind clinical study was conducted to determine and compare the efficiency of honey , chamomile and normal saline mouthwash for the treatment of oral mucositis. The study was conducted on 83 patients who undergoing radiation therapy and have oral mucositis. ANOVA and ‘t’test was used for data analysis. Significant difference was found between honey, chamomile and normal saline group in the score of severity of mucositis ($p=0.017$), mucositis pain ($p=0.027$). The findings indicated that honey and

chamomile have equal efficiency in radiation therapy induced oral mucositis as compared to the normal saline group.

Gulavita, S et al.,(2010)performed a randomized double blind study was conducted to determine whether normal saline could alleviate radiation induced oral mucositis. Patients were scheduled to receive radiation therapy to include greater than one third of oral cavity mucosa were selected for the study. Twenty five patients were randomized to receive the normal saline, while twenty four received placebo mouthwash. The result showed that normal saline provided benefit to patient undergoing radiation therapy to the oral mucosa and suggesting that normal saline is determental in clinical situation.

Biswal,et al.,(2010) had conducted a study in the Department of Oral Medicine and Radiology, Tamilnadu Government Dental College and Hospital, Chennai,. The sample size comprised of 60 patients, of both genders, diagnosed with oral malignancy clinically and histopathologically and planned for radiotherapy. The patients were assigned into three groups by random sampling. Each group consisted of 20 patients. Group 1 patients were instructed for topical application of natural honey, groups 2 and 3 were instructed for topical application of 0.15% benzydamine hydrochloride and 0.9% normal saline respectively. The onset of mucositis and the severity of mucositis were graded during the course of the radiotherapy and two weeks after radiotherapy, with WHO mucositis grading in all the three groups and statistically analysed with SPSS version 11 software. A significant reduction in mucositis in honey-received patients compared with 0.15% benzydamine hydrochloride, 0.9% normal saline applied patients occurred. The differences between the groups were statistically significant ($P < 0.001$).Pure natural honey can be an effective agent in managing radiation induced oral mucositis. Honey could be a simple, potent and inexpensive agent, which is easily available, and it can be a better therapeutic agent in managing radiation mucositis in developing countries like India for the management of this morbidity.

Miranzadeh.,(2010)conducted a study to assess the effectiveness of chemotherapy-induced oral mucositis referred to Shahid Beheshti Medical Center, Kashan, Iran. The data collection instrument had two-part; a demographic part and another part recording the severity of the mucositis at the first, seventh, and 14th days

of the intervention based on a WHO criteria checklist in 2005. In this study, 56 patients diagnosed with cancer were randomly assigned into control and experimental groups in similar blocks according to their mucositis severity. The experimental group gargled 15 mL of a routine solution mixed with Yarrow distillate 4 times a day for 14 days while the control group gargled 15 mL of routine solution. The severity of mucositis was assessed at the beginning of the intervention, and then after 7 and 14 days of the study. Data were analyzed using chi-square and Fisher exact test, Mann-Whitney U, Kruskal-Wallis, and Friedman tests using SPSS 11.5 software. At first, the median score of mucositis in the experimental group was 2.50 that significantly reduced to 1 and 0 in days 7 and 14 of the intervention, respectively (P value < 0.001). However, in the control group, the median score of mucositis was 2.50, which significantly increased to 3 in days 7 and 14 (P value < 0.001).*Yarrow* distillate-contained solution reduced mucositis severity more than the routine solution. Therefore, we suggest using it in patients with chemotherapy-induced mucositis.

Stockman, M.A.,(2009)had conducted a study to evaluate the effectiveness of intervention for the prevention and management of oral mucositis in cancer patients treated with head and neck radiotherapy and radiation therapy by using randomized clinical trials. The main aim of the study was the prevention of oral mucositis in cancer patients undergoing head and neck radiation. The Meta analysis included 45 studies in which different interventions were evaluated. The interventions were local application of honey and normal saline , oral cooling and administration of amifosline. The results showed that no single intervention completely prevent or treat oral mucositis.

Kumar,M., (2008) had conducted a study to evaluate the effect of three alcohol-free mouthwashes on radiation-induced oral mucositis in patients with head and neck malignancies. Eighty patients with head and neck malignancies, scheduled to undergo curative radiotherapy, were randomly assigned to receive one of the two applications(normal saline ,honey) or a control. The patients were instructed to rinse with 10 ml of the solution, twice a day, for a period of 6 weeks. Mucositis was assessed at baseline and at weekly intervals during radiation therapy, using the World Health Organization criteria for grading of mucositis. Among the 76 patients who completed the study, patients in the honey group had significantly lower mucositis

scores when compared to the study group 11 from the first week of radiotherapy. Their scores were also significantly lower when compared to the normal saline groups from the fourth and fifth week, respectively, after radiotherapy. This study shows that use of honey can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

Fleischer,W., (2007) prospective randomized controlled trial was conducted to assess the efficiency of honey on radio and radiation therapy treatment with 40 patients undergoing radiation or radiation therapy in head and neck region. Twenty patients rinsed honey four times daily while other group for comparison rinsed with sterile water. Clinical examination of oral mucositis was done weekly. In honey group the mean oral mucositis grade was 1 and in the comparison group mean oral mucositis grade was 3. The study also showed that duration of healing of oral mucositis in honey group was 2.75 weeks and in the study group 11 it was 9.25 weeks. This showed that the incidence, severity and duration of radiotherapy and radiation therapy induced oral mucositis can be significantly reduced by oral rinsing with honey.

Potting,C., (2006)conducted a study the effectiveness of commonly used mouthwashes for the prevention and treatment of radiation therapy-induced oral mucositis: a systematic review of daily chlorhexidine was often recommended for preventing radiation therapy-induced oral mucositis. honey, NaCl 0.9%, water salt soda solution and chamomile mouthwash were also recommended. However, the effectiveness of these mouthwashes was unclear. A systemic review was conducted to assess the effectiveness of mouthwashes in preventing and treating radiation therapy-induced oral mucositis. Based on study quality, three out of five randomized controlled trials were included in a meta-analysis. The results failed to detect any beneficial effects of chlorohexidine as compared with sterile water, or NaCl 0.9%. The severity of oral mucositis was shown to be reduced by 30% using a honey as compared in a single randomized controlled trial. These results do not support the use of chlorohexidine mouthwash to prevent and treat oral mucositis.

Reimer, W., (2004) performed a randomized controlled trail double blind was conducted to assess the effectiveness of commonly used mouthwash for the

prevention and treatment of radiation therapy induced oral mucositis. Patients undergoing radiation therapy were included in this study. The severity of mucositis was scored using a WHO instrument. Severity was assessed daily, weekly or less often. The mouthwashes used for this study were normal saline, honey and chamomile mouthwash. A result shows that normal saline was not found to be more effective than honey and with chamomile mouthwash. There was no difference in incidence or severity of oral mucositis.

CHAPTER- III

RESEARCH METHODOLOGY

This chapter deals with the methodology adapted to this study. It includes Research approach, Research design, Variables, Setting, Population, Sample, Sample size, and Criteria for sample selection, Sampling technique, Description of tool, Content validity, Pilot study, Reliability, Method of data collection, Plan for data analysis and Ethical considerations.

Research approach

The researcher utilized Quantitative research approach.

Research design

Pre test and post test control group design was adopted in this study.

GROUP	PRE TEST (phase 1)	INTERVENTION (phase 2)	POST ASSESSMENT (phase 3)
Study group	O_1	X_1	O_2
control group	O_1	-	O_2

O_1 - Oral mucositis assessment on first day of radiation with or without chemo therapy.

X_1 - Natural honey application

O_2 - Oral mucositis assessment on seventh day of radiation with or without chemo therapy.

Variables:

Independent variable - Natural honey

Dependent variable - oral mucositis

Setting:

The study was conducted in C.S.I medical mission hospital, International Cancer Centre, Neyyoor Kanyakumari District, which is run by the Church of South India (C.S.I) Medical Mission Hospital, Neyyoor. It is situated 10 kilometres away from St. Xavier's Catholic College of Nursing, Chunkankadai, Nagercoil**.** C.S.I Medical Mission Hospital is a 500 beded hospital, which comprises of various wings

like Oncology, Cardiology, General Surgery, General Medicine, Ophthalmology, Ear Nose and Throat, Orthopaedics, Intensive Care Units, Paediatric, Maternity, Nephrology, Dialysis. The Oncology unit consists of 40 beds for General wards for males and females and 20 beds for Private wards. It has well equipped radiation therapy unit. Linear accelerator was used to provide radiation therapy for the patients. Averagely 5000 patients get treatment in outpatient and 2000 patients get treatment in inpatient in a year.

Population:

- **Target population**

The population under study constituted all the patients undergoing radiation therapy with or without chemo therapy with oral mucositis.

- **Accessible population**

All the patients undergoing radiation therapy with or without chemo therapy with oral mucositis who were admitted in C.S.I medical mission hospital, International Cancer Centre, Neyyoor

Sample:

Patients undergoing radiation therapy who fulfilled the inclusion criteria who were admitted in C.S.I medical mission hospital, International Cancer Centre, Neyyoor.

Sample Size:

Sample size was 60, out of which 30 samples were in the study group and 30 samples were in the control group.

Sampling technique:

Purposive sampling technique was adopted to select the patients with oral mucositis in study group and control group.

Criteria for sample selection:

- **Inclusion criteria**
  - Patients who were undergoing radiation therapy with or without chemo therapy.
  - Patients who were undergoing radiation therapy with or without chemotherapy between the age of 30- 70years.
- **Exclusion criteria**
  - Patients who were undergoing radiation therapy in the condition of critically ill.
  - Patients who were undergoing radiation therapy having other hereditary diseases like facial paralysis.
  - Patients who were undergoing radiation therapy with or without chemotherapy not willing to participate
  - Patients who were undergoing radiation therapy with or without chemotherapy with grade 4.

Description of tool

The tool used in this study has 3 parts.

Part – 1[ANNEXURE: vii]

A structured questionnaire to collect the demographic variables such as age, gender, place of residence, religion, type of family, marital status, educational status and occupation.

A structured questionnaire to collect the clinical variables such as type of diet, duration of illness, and number of radiation therapy.

Part – 2

WHO Oral Mucositis Grading Scale [ANNEXURE: vii]

This scale is intended to record the own assessment of any erythema, ulcerative state of the patient that have been experienced. It indicates the estimate of any difficulty while moving the facial muscles onset.

Scoring

Grade 0: no changes

Grade 1: mild

Grade 2: moderate

Grade 3: severe

Grade 4: life-threatening

Description of the intervention

Procedure for assessment

The researcher measured the oral mucositis by WHO Oral Mucositis Grading Scale from the study group and control group.

Procedure Session: [ANNEXURE: xi]

The researcher arrange the articles with a tray containing natural honey 10m.l, bowl, gauze pieces, artery forceps .Assemble the articles nearer to the bed side. Explain the procedure to the patient. The researcher makes the patient to sit in comfortable position. Wash the hands .Wear the Gloves, then apply the natural honey over the mucositis area with the help of artery forceps and gauze for 15 minutes. The researcher makes the patient back in comfortable position.

Content validity: [ANNEXURE: v]

Content validity of the tool was ascertained by the expert opinion from 2 Medical practitioners and 3 Nursing experts. The experts gave their opinions and suggestions for further modification of items to improve the clarity and content of the question. The standardized tool of WHO Oral Mucositis Grading Scale was used.

Reliability

Standardised tool of WHO Oral Mucositis Grading Scale was used to assess oral mucositis**.** The reliability value was 0.9

Pilot study:

Pilot study was conducted in Holy cross hospital Vetnoornimadam, after undergoing oral consent from administrative officer of Holy cross hospital Vetnoornimadam. The pilot study was conducted in Holy cross hospital

Vetnoornimadam. Among 6 patients 3 were in study group and 3 were in control group who were selected. Then pre assessment was done with the help of WHO oral mucositis scale. The intervention was given with natural honey for study group. Then the post assessment was conducted on the seventh day. Analysis of the data was done by using descriptive and inferential statistics. The tool was reliable and tool scoring was found feasible and practicable. No changes were made and researcher proceeded for main study.

Procedure for data collection:

The researcher obtained formal approval from the Principal of St. Xavier's Catholic College of Nursing and the Medical and Nursing Superintendent department head of oncology of the C.S.I. Mission Hospital, Neyyoor, the researcher proceeded with the data collection after obtaining the oral consent.

Phase 1

Purposive sampling technique was used to assess the effectiveness of natural honey on oral mucositis. The data was collected with the selected participants and the WHO Oral Mucositis Grading Scale standardized tool was used to assess the oral mucositis in study and control group.

Phase 2:

In study group, after the pre assessment to the patients, The researcher arrange the arrange the articles with a tray containing natural honey 10 m.l, bowl, gauze pieces ,artery forceps .Assemble the articles nearer to the bed side . Explain the procedure to the patient. The researcher makes the patient to sit in comfortable position. Wash the hands .Wear The Gloves, then apply the natural honey over the mucositis area with the help of artery forceps and gauze for 15 minutes. The researcher makes the patient back in comfortable position. In control group, the samples were proceeded with routine care in the hospital.

Phase 3

In study group the selected patients were assessed on the 7th day of intervention and control group also the selected patient's were assessed on the 7th day of intervention.

Ethical consideration

The study was conducted after the approval of the dissertation committee of St. Xavier's Catholic College of Nursing. Permission was obtained from the International Cancer Centre, Neyyoor, Kanykumari District. Oral consent was obtained from each subject before starting the data collection. Assurance was given to the study participants regarding the confidentiality of the data collected.

Plan for analysis

Data collected was analysed by using both descriptive and inferential statistics such as mean, standard deviation, chi square, paired test and unpaired test.

Descriptive statistics

Mean and standard deviation was used to assess the effectiveness of natural honey on oral mucositis.

Inferential statistics

Oral mucositis on study group and control group. Paired't' test was used to compare post assessment level of oral mucositis on study group and control group. Chi-square was used to find out the association of post assessment oral mucositis among patients undergoing radiation therapy between the study group and control group with the selected demographic variables.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of the data collected among patients undergoing radiation therapy with or without chemotherapy. This chapter also represents the findings of the study. The data collected from the samples were tabulated, analysed and preserved in the tables and interpreted under the following sections based on the objectives and hypotheses of the study. This chapter is divided into three sections.

Section A: **1.** Distribution of demographic variables and clinical variables of Patients with oral mucositis in study group and control group.

1.1 Frequency and percentage distribution of demographic variables of patients with oral mucositis in study group and control group.

1.2 Frequency and percentage distribution of clinical variables of patients with oral mucositis in study group and control group.

Section B: **2.**Pre assessment of patients with oral mucositis in study and control group**.**

2.1 Pre assessment frequency and percentage distribution of patients with oral mucositis in study and control group**.**

Section C:

3. Post assessment of patients with oral mucositis in study and control group**.**

3.1 Post assessment frequency and percentage distribution of patients with oral mucositis in study and control group**.**

Section D:

4.Comparison of pre assessment and post assessment of patients with oral mucositis in study group and control group .

4.1Comparison of pre assessment and post assessment of patients with oral mucositis in study group and control group.

4.2Comparison of post assessment of patients with oral mucositis in study group and control group.

Section E:

5. Association between the post assessment of oral mucositis among Patients in study group and control group with the selected demographic Variables and clinical variables.

5.1Association between the post assessment of oral mucositis among patients in study group with the selected demographic variables.

5.2Association between the post assessment of oral mucositis among patients in study group with the selected clinical variables.

5.3Association between the post assessment of oral mucositis among patients in control group with the selected demographic variables

5.4Association between the post assessment of oral mucositis among patients in control group with the selected clinical variables

SECTION-A

DISTRIBUTION OF DEMOGRAPHIC VARIABLES AND CLINICAL VARIABLES OF PATIENTS WITH ORAL MUCOSITIS IN STUDY GROUP AND CONTROL GROUP.

Table 1.1 Frequency and percentage distribution of demographic variables of patients with oral mucositis in study group and control group

N = 60

S. No	Demographic variables	Study group (n=30)		Control group (n=30)	
		f	%	f	%
1	**Age**				
	a) 31-40 yrs	4	13.33	6	20
	b) 41-50 yrs	8	26.67	6	20
	c) 51-60 yrs	12	40	10	33.33
	d) >61 yrs	6	20	8	26.67
2	**Gender**				
	a) Male	18	60	16	53.33
	b) Female	12	40	14	46.67
3	**Place of residence**				
	a) Rural	16	53.33	18	60
	b) Urban	14	46.67	12	40
4	**Religion**				
	a) Hindu	18	60	16	53.33
	b) Christian	10	33.33	12	40
	c) Muslim	2	6.67	2	6.67
	d) Others	0	0	0	0
5	**Marital status**				
	a) Married	30	100	30	100
	b) Unmarried	0	0	0	0
	c) Widow/widower	0	0	0	0
	d) Separated	0	0	0	0
6	**Education**				
	a) Illiterate	0	0	0	0
	b) Primary	12	40	14	46.67
	c) Secondary	12	40	10	33.33

	d) Graduate and others	6	20	6	20
7	**Occupation**				
	a) Government	4	13.33	3	10
	worker	6	20	9	30
	b) Private worker	10	33.33	11	36.67
	c) Self worker	10	33.34	7	23.33
	d) Unemployment				

Table 1.1 represents the distribution of patients with oral mucositis, according to age in study group 4 (13.33%) were in the age group between 31-40 years, 8 (26.67%)were in the age group between 41-50 years, 12 (40%) were in the age group between 51-60 years,6(20%) were in the age group of above 61 years . In control group 6(20 %) were in the group between 31-40 years, 6 (20%)were in the age group between 41-50 years, 10 (33.3%) were in the age group between 51-60 years, 8(26.67%) age group of above 61 years.

Regarding the gender, in study group 18 (60%) were males, 12 (40%) were females. In control group 16 (53.33%) were males, 14(46.67%) were females.

Regarding the place of residence, in study group 18 (60%) belongs to the rural area,12 (40%) belongs to the urban area. In control group 16(53.33 %) belongs to the rural area, 14(46.67%) belongs to the urban area.

With regard to religion, in study group 18 (60%) were Hindu religion, 10 (33.33%) were Christian,2(6.67%) were Muslim. In control group 16(53.33%) were Hindu religion, 12(40%) belongs to Christian, 2(6.67%) belongs to Muslim.

Among the marital status 30(100%) were married in study group and control group.

With regard to educational status, in study group 12(40%) were belongs to primary education, 12(40%) belongs to higher secondary and 6(20%) belongs to graduate and others. In control group 14(46.67%) were belongs to primary education, 10(33.33%) belongs to higher secondary and 6(20%) belongs to graduate and others.

With regard to occupation, in study group 4 (13.33%) were government workers, 6(20%) were private workers, 10(33.33%) were self-workers and 10(33.34%) were unemployed. In control group 3 (10%) were government workers,

9(30%) were private workers, and 11(36.67%) were self-workers,7(23.33%) were unemployed.

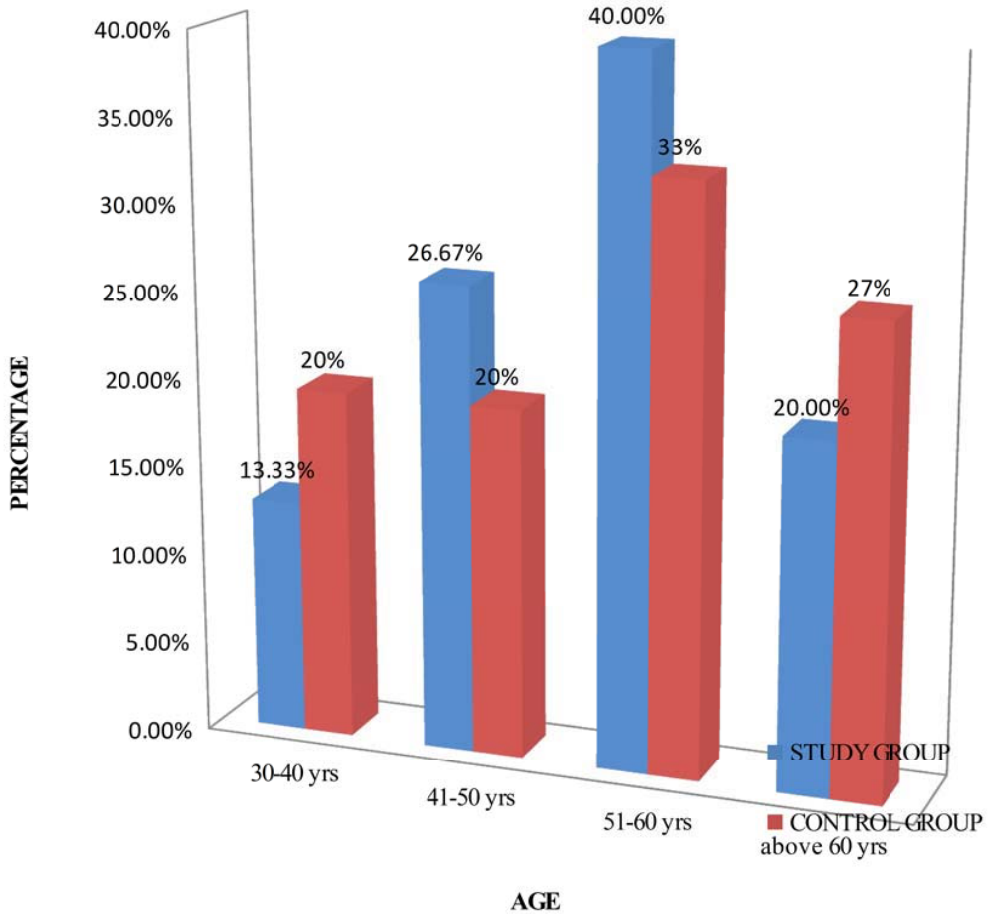

Fig-1.11: Percentage distribution of age among patients undergoing radiation therapy with or without chemotherapy.

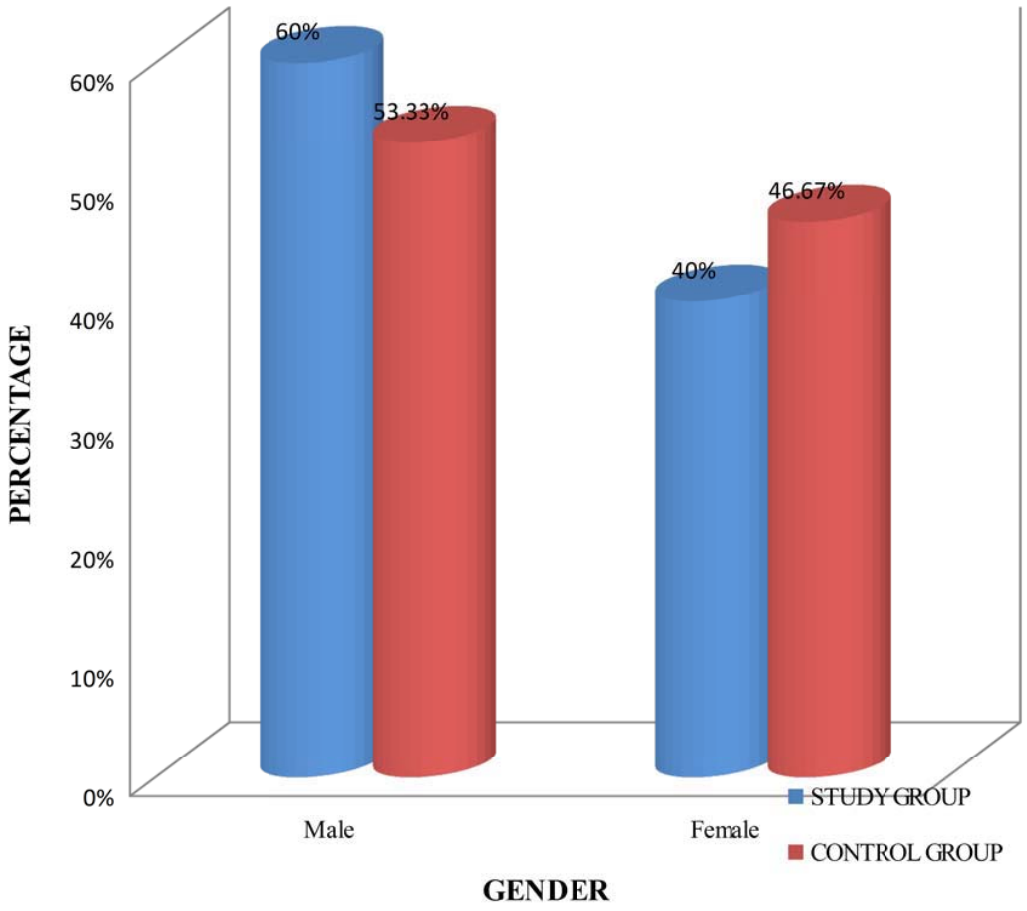

Fig1.12: Percentage distribution of gender among patients undergoing radiation therapy with or without chemotherapy.

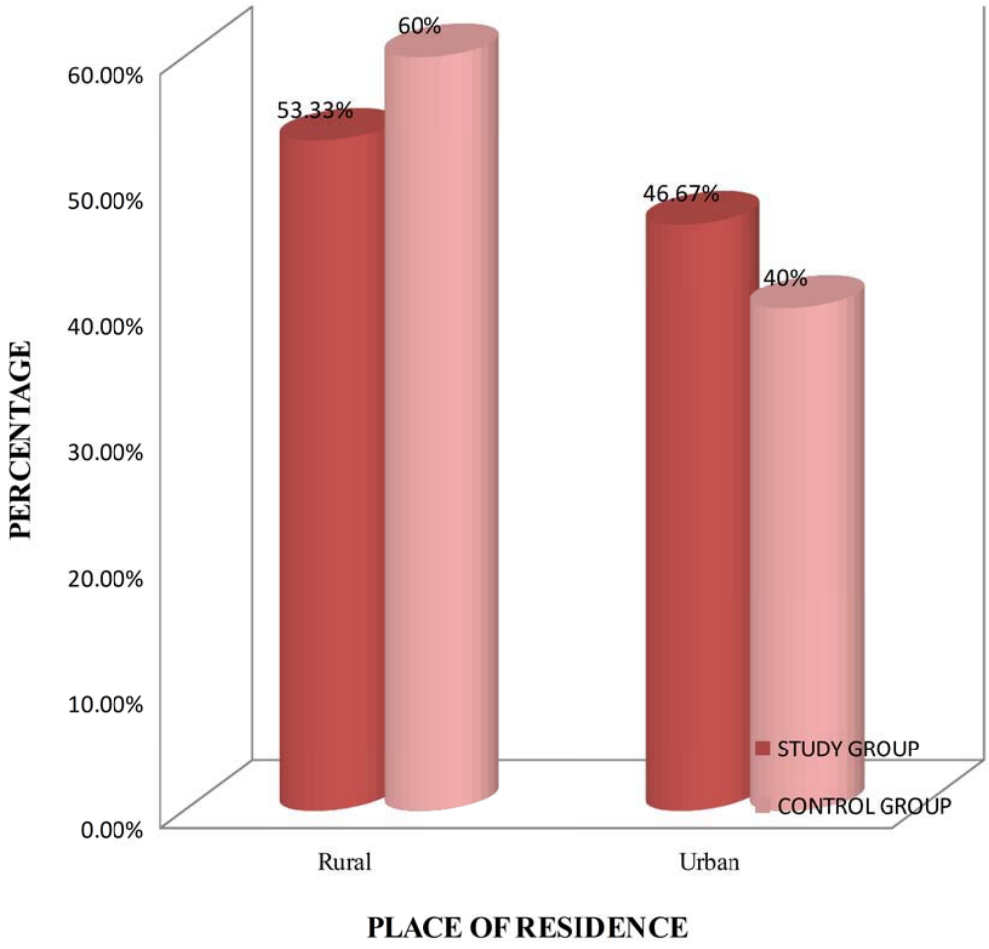

Fig-1.13: Percentage distribution of place of residence among patients undergoing radiation therapy with or without chemotherapy

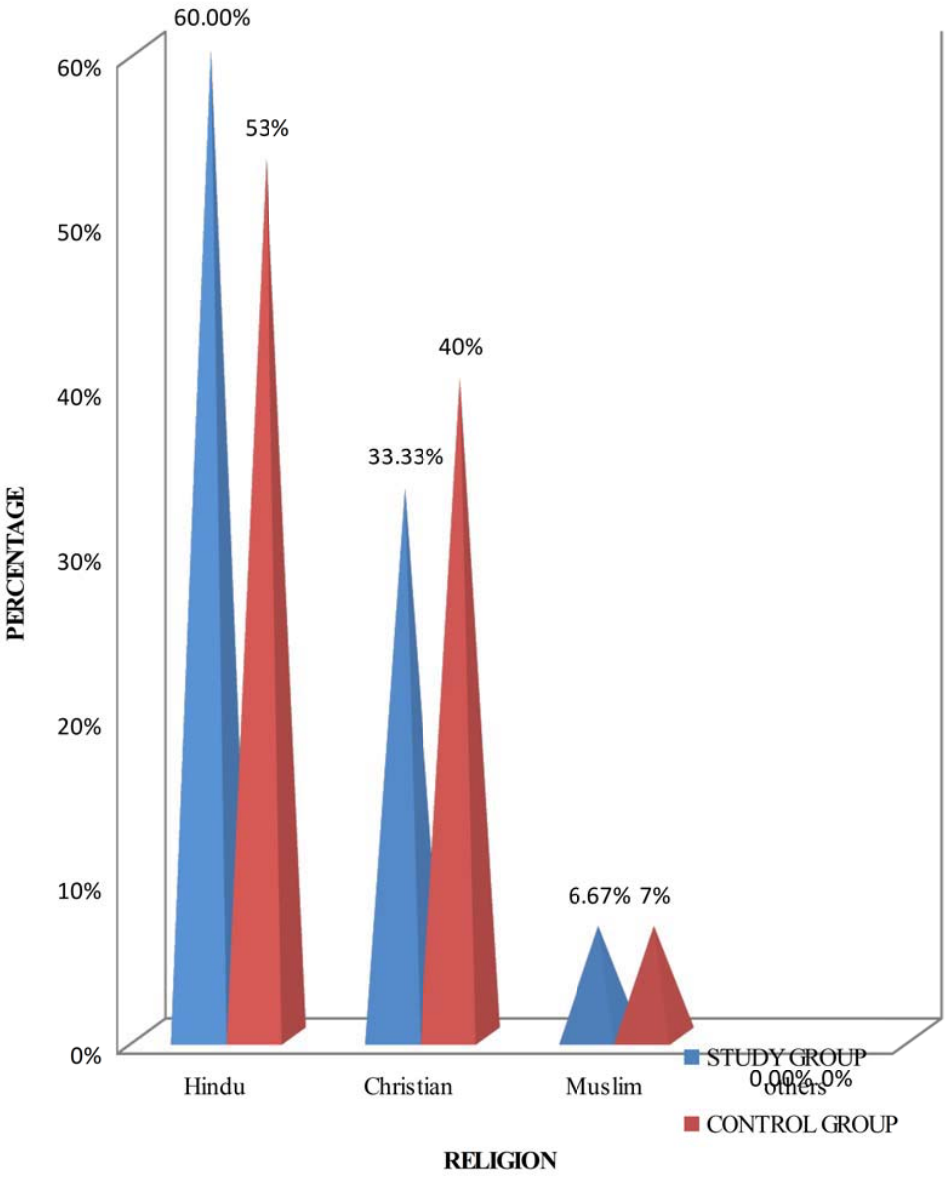

Fig -1.14: Percentage distribution of religion among patients undergoing radiation therapy with or without chemotherapy

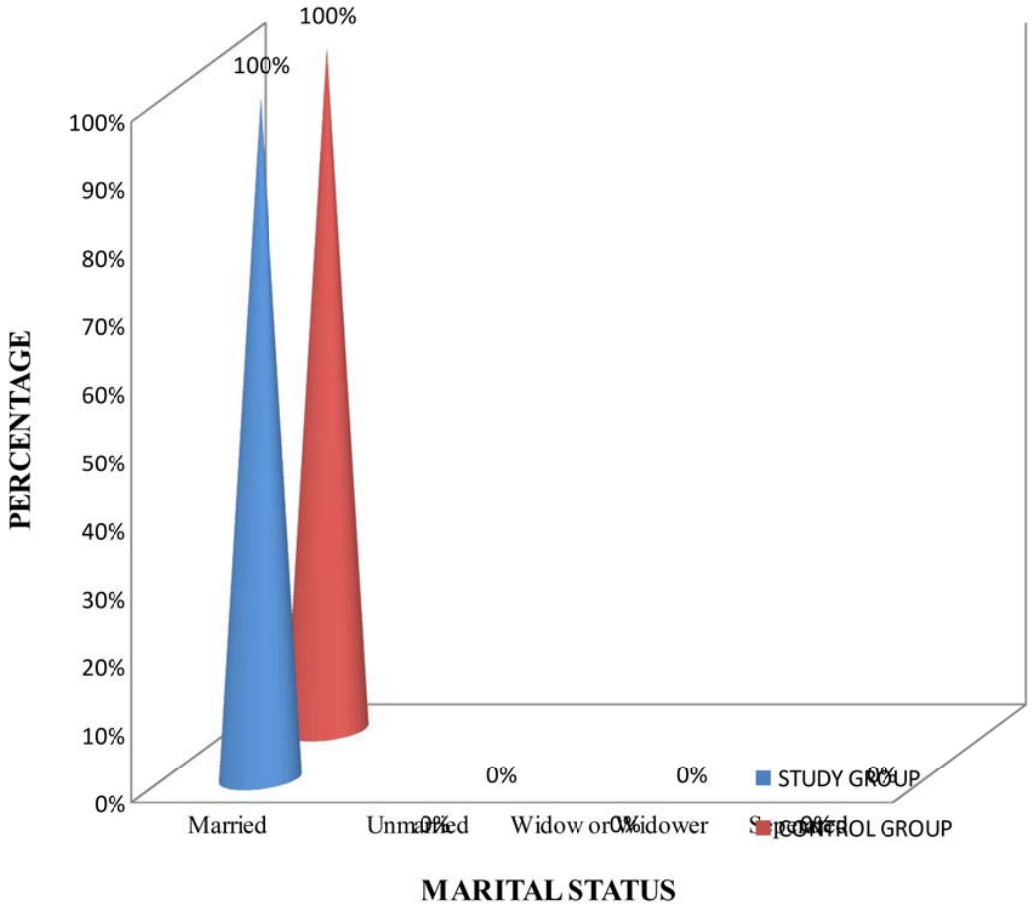

Fig-1.15: Percentage distribution of marital status among patients undergoing radiation therapy with or without chemotherapy.

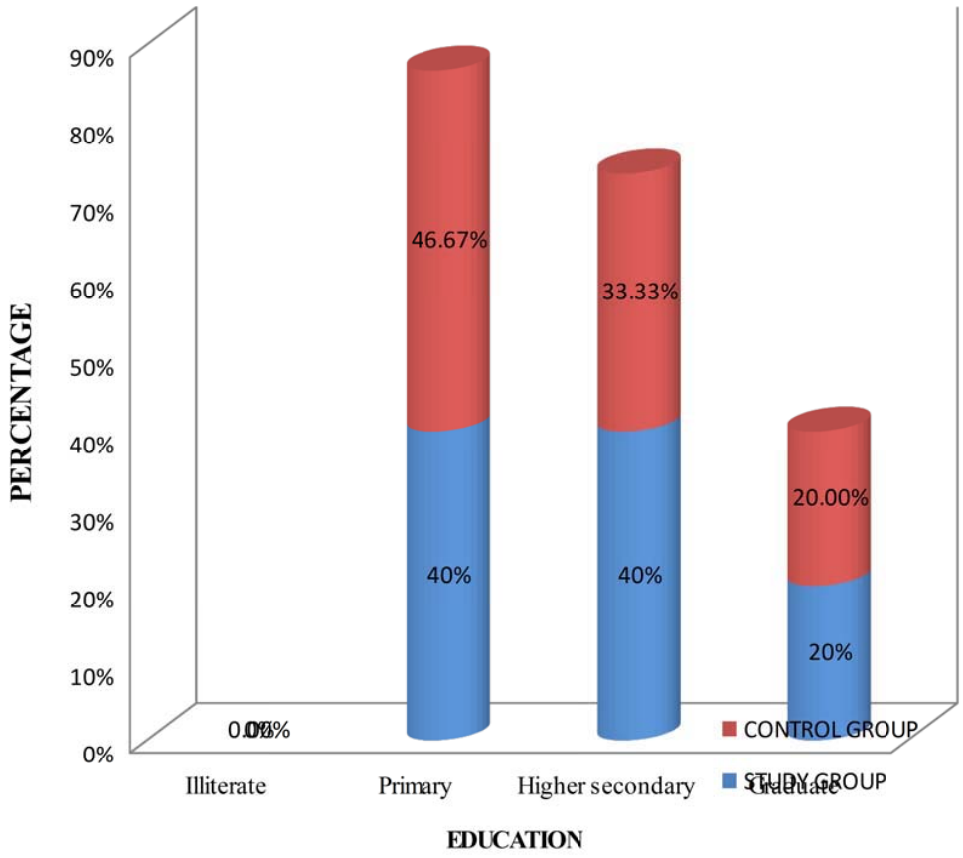

Fig1.16: Percentage distribution of education among patients undergoing radiation therapy with or without chemotherapy.

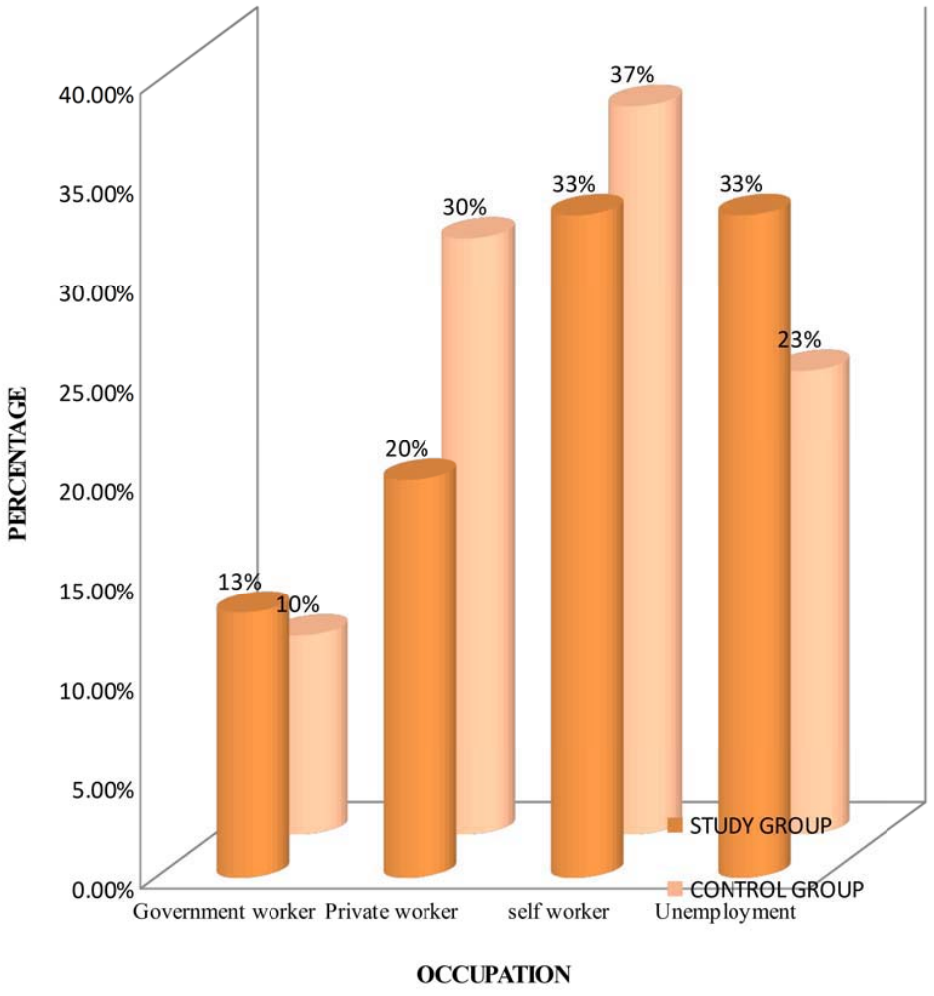

Fig-1.17: Percentage distribution of occupation among patients undergoing radiation therapy with or without chemotherapy

Table 1.2 Frequency and percentage distribution of clinical variables of patients with oral mucositis in study group and control group

N = 60

S. No	Clinical variables	Study group (n=30)		Control group (n=30)	
		f	%	f	%
1	**Type of diet** **a)** Vegetarian **b)** Non vegetarian	 0 30	 0 100	 0 30	 0 100
2	**Duration of illness** a) 0-12 months. b) 13-24 months. c) 25-36 months. d) >37 months.	 8 10 8 4	 26.67 33.33 26.67 13.33	 9 13 6 2	 30 43.33 20 6.66
3	**Number of exposure to radiation therapy** a) 0 – 2times b) 3 - 5 times c) 6 – 8times d) > 9 times	 12 12 6 0	 63.33 23.33 13.33 0	 13 12 5 0	 43.33 40 16.67 0
4	**Cycle of chemotherapy** **a)** 1cycle **b)** 2 cycle **c)** 3cycle	 19 7 4	 60 23.33 13.33	 13 12 5	 43.30 40 16.66

Table 1.2 represents the distribution of patients with oral mucositis according to dietary pattern of patients with oral mucositis, 30(100%) were non vegetarian in study and control group.

With regard to duration of illness, In study group 8 (26.67%) had 0-12 months of duration, 10(33.33%) had 13-24 months of duration, 8(26.67%) had 25-36 months of duration and 4(13.33%) had more than 37 months of duration. In control group 9 (30%) had 0-12 months of duration, 13 (43.33%) had 13-24 months of duration, 6 (20%) had 25-36 months of duration and 2(6.66%) had more than 37 months of duration.

Regarding to number of radiation therapy , in study group 12 (40%) had 0 – 2 times of exposure to radiation therapy, 12(40 %) had 3 -5 times of exposure to radiation therapy,6(20%)had 6 -8 times of exposure to radiation therapy. In control group 13 (43.33%) had 0 – 2 times of exposure to radiation therapy, 12(40 %) had 3-5 times of exposure to radiation therapy ,5(16.67%)had 6 -8 times of exposure to radiation therapy .

With regard to cycle of chemotherapy, in study group 19 (63.33%) had first cycle of chemotherapy, 7(23.33%) had second cycle of chemotherapy ,4(13.33%)had third cycle of chemotherapy. In control group 13 (43.3%) had first cycle of chemotherapy, 12 (40%) had second cycle of chemotherapy, 5(16.6 %) had third cycle of chemotherapy.

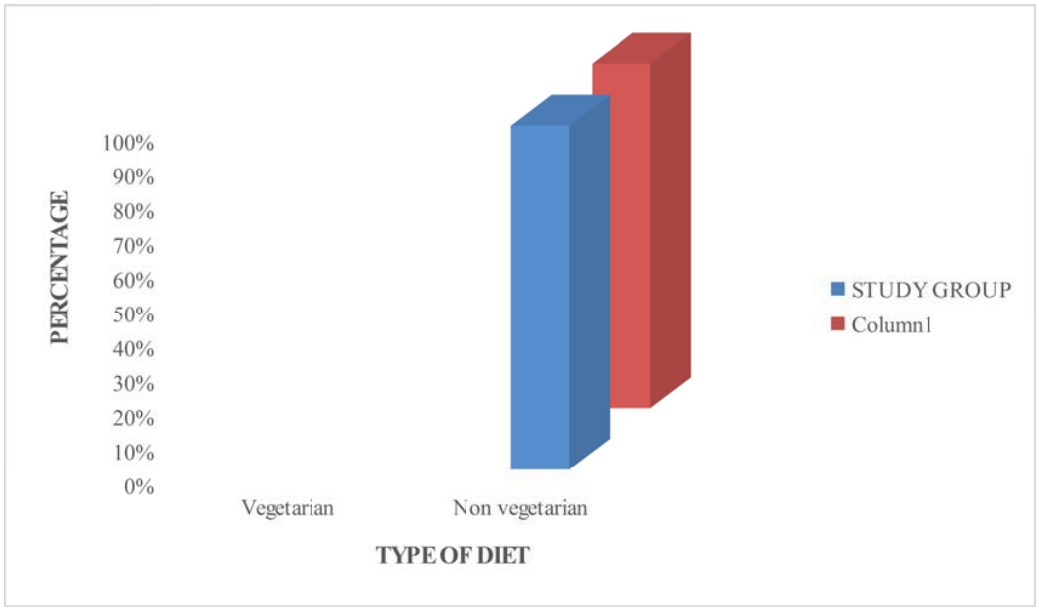

Fig-1.18: Percentage distribution of type of diet among patients undergoing radiation therapy with or without chemotherapy.

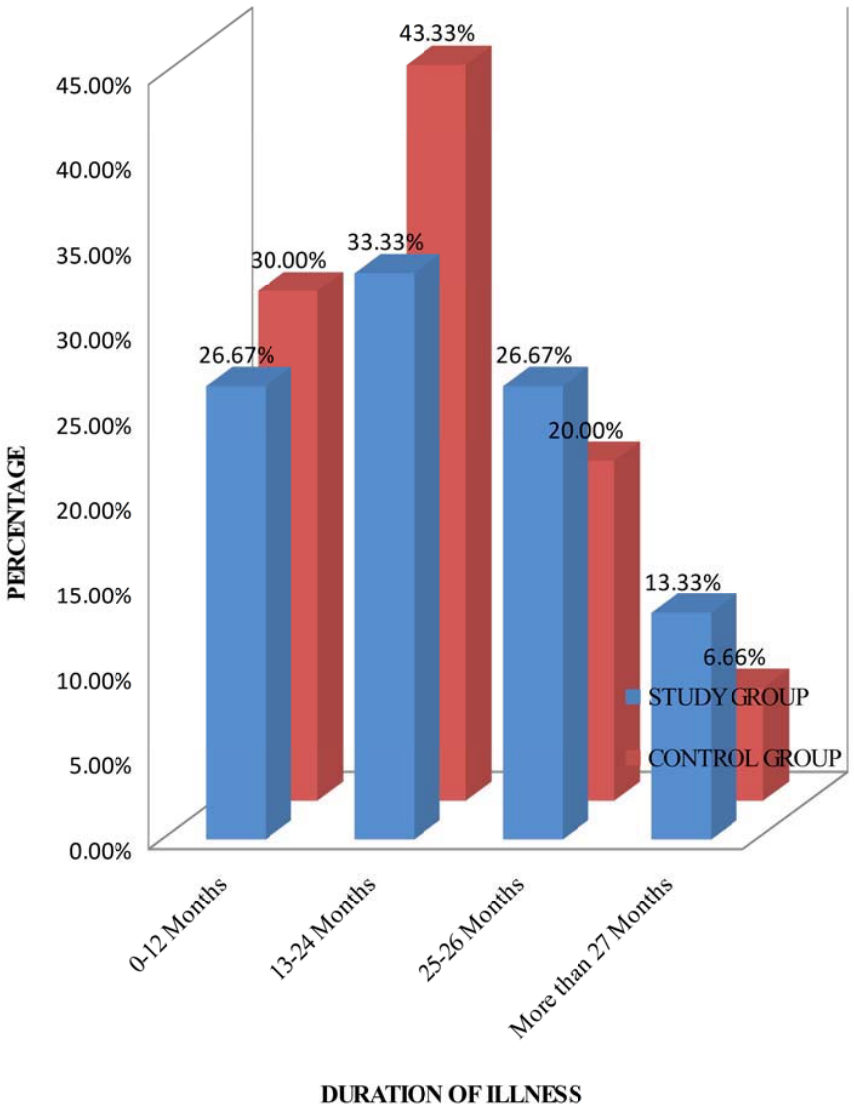

Fig-1.19: Percentage distribution of type of diet among patients undergoing radiation therapy with or without chemotherapy.

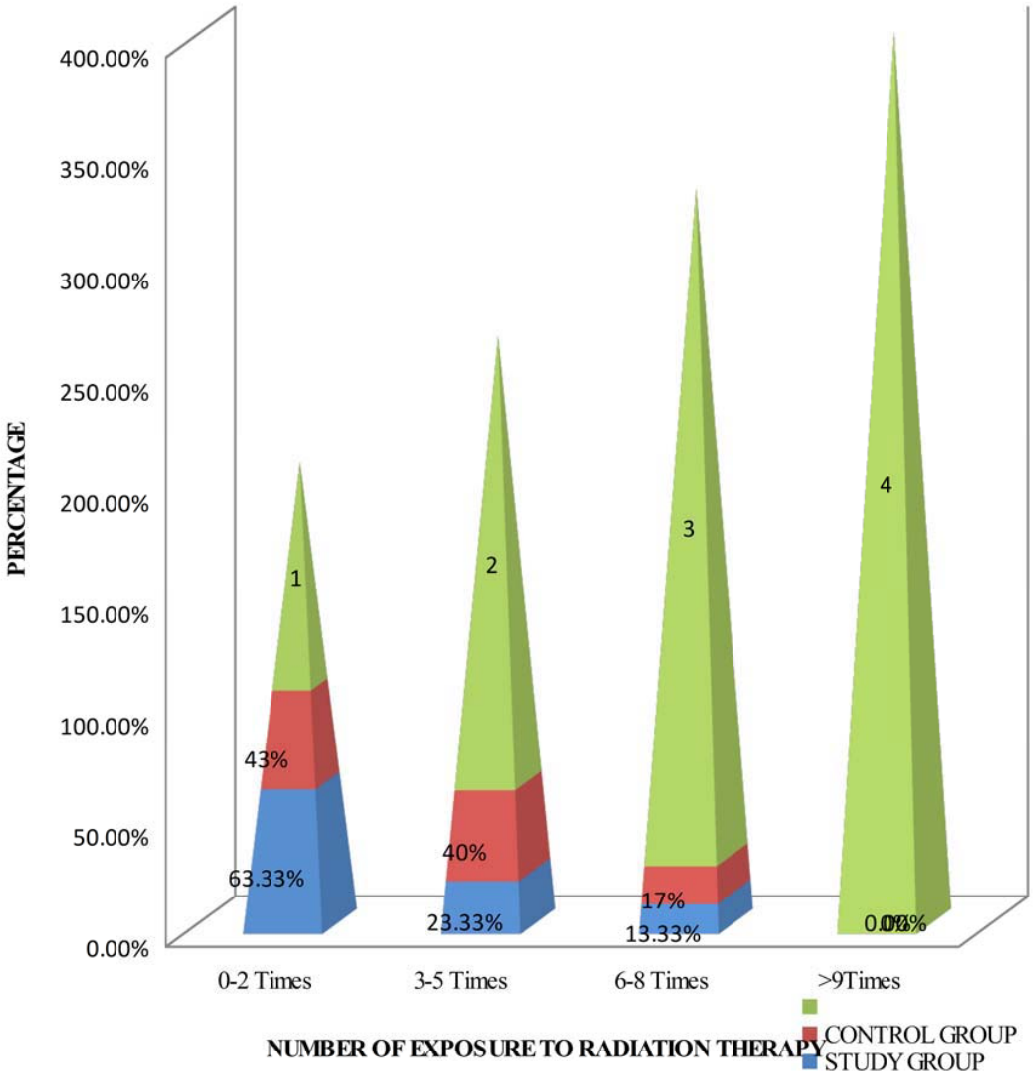

Fig-1.20: Percentage distribution of number of exposure to radiation therapy among patients undergoing radiation therapy with or without chemotherapy

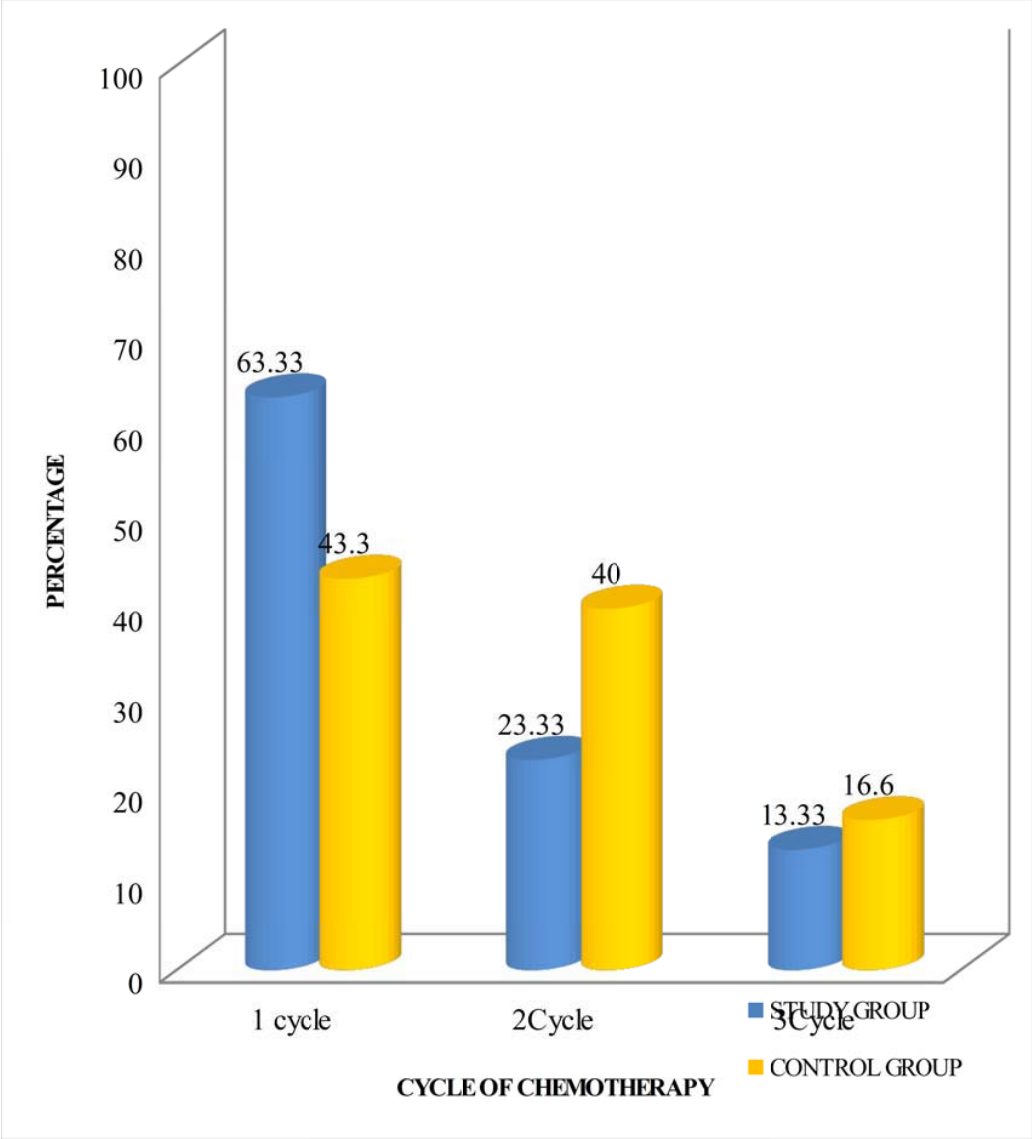

Fig-1.21: Percentage distribution of cycle of chemotherapy among patients undergoing radiation therapy with or without chemotherapy

SECTION-B

PRE ASSESSMENT OF PATIENTS WITH ORAL MUCOSITIS IN STUDY AND CONTROL GROUP.

2.1 Pre assessment frequency and percentage distribution of patients with oral mucositis in study and control group

N=60

S. No	Level of oral mucositis	Study group (n=30)		Control group (n=30)	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
1	No changes	0	0	0	0
2	Mild oral mucositis	0	0	0	0
3	Moderate oral mucositis	11	36.67	12	40
4	Severe oral mucositis	19	63.33	18	60

Table 2 .1 represent, during pre-assessment,. In study group 11(36.67%) had moderate oral mucositis and 19(63.33%) had severe oral mucositis. In control group, 12(40%) had moderate oral mucositis, 18(60%) had oral mucositis.

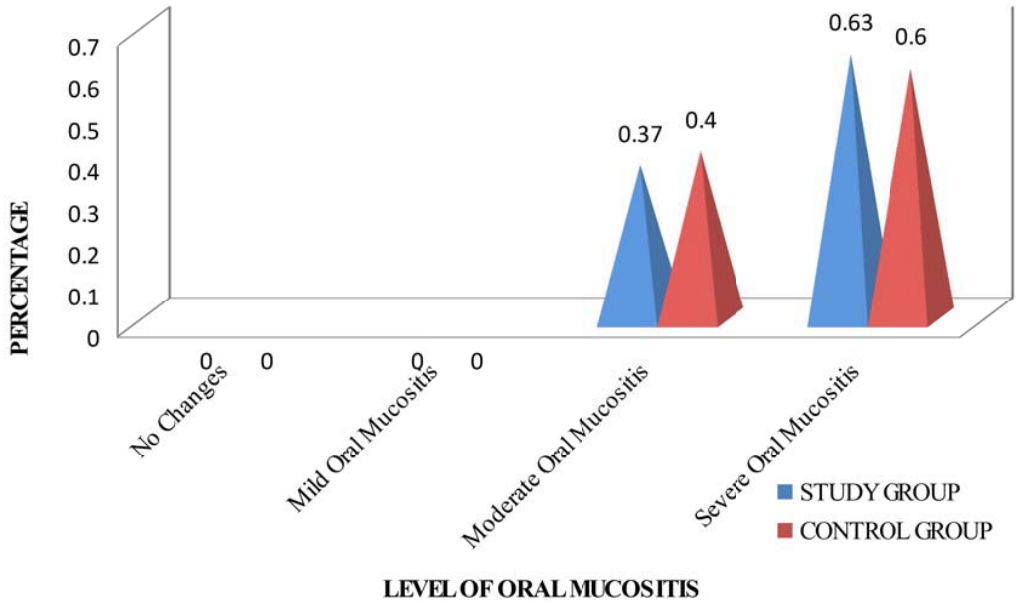

Fig1.22 Pre assessment percentage distribution of patients with oral mucositis in study and control group

SECTION 3

POST ASSESSMENT OF PATIENTS WITH ORAL MUCOSITIS IN STUDY AND CONTROL GROUP.

Table 3.1 Post assessment frequency and percentage distribution of patients with oral mucositis in study and control group.

N=60

S.No	Level of oral mucositis	Study group (n=30)		Control group (n=30)	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
1	No changes	0	0	0	0
2	Mild oral mucositis	12	40	4	13.33
3	Moderate oral mucositis	11	36.67	14	46.67
4	Severe oral mucositis	7	23.33	12	40

. Table 3.2 represent that, during post assessment, in study group 26(87%) had moderate oral mucositis and 4(13.33%) had severe oral mucositis. In control group none of them had mild level of oral mucositis, 27(90%) had moderate oral mucositis, 3(10%) had severe oral mucositis, and no patients with oral mucositis in life threatening oral mucositis

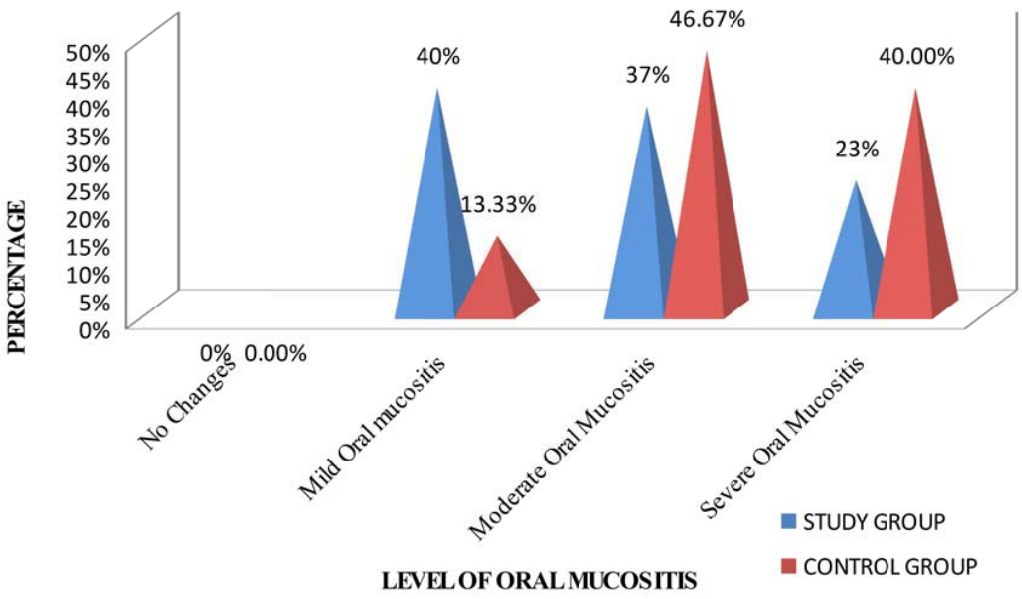

Fig 1.23 Post assessment frequency and percentage distribution of patients with oral mucositis in study and control group

SECTION: D

4.1Comparison of pre assessment and post assessment of patients with oral mucositis patients in study group and control group

N=60

S.No	Group	Mean	SD	Paired 't' value	df	Table value
1	Study group(n=30)					
	Pre assessment	2.69	1.83	9.05	29	2.042
	Post assessment	0.49	0.79			
2	Control group(n=30)					
	Pre assessment	2.60	2.26	3.80	29	2.043
	Post assessment	0.49	0.69			

Table- 4.1 represents, the mean score on level of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group the mean post assessment value was 0.49 and the standard deviation was 0.79 and in the control group the mean post assessment was0.49 and the standard deviation was 0.69. The mean difference was high and statistically significant. That is natural honey application was effective to reducing the oral mucositis among patients undergoing radiation therapy with or without chemotherapy

4.2Comparison of post assessment of patients with oral mucositis in study group and control group

N=60

S.no	Group	Mean	SD	't' test	df	Table value
1	Study group	1.83	2.26	2.36	58	2.0
2	Control group	0.79	0.69			

Significant at p<0.05 level

Table- 4.2represents, the mean score of patients with oral mucositis in study group the mean post test value was 1.83 and the standard deviation was 2.26 and in the control group the mean post test was0.79 and the standard deviation was 0.69. The mean difference was high and statistically significant. That is natural honey application was effective for reducing the oral mucositis among patients undergoing radiation therapy with or without chemotherapy.

SECTION: E

ASSOCIATION BETWEEN THE POST ASSESSMENT OF ORAL MUCOSITIS AMONG PATIENTS IN STUDY GROUP AND CONTROL GROUP WITH THE SELECTED DEMOGRAPHIC VARIABLES AND CLINICAL VARIABLES

5.1Association between the post assessment of oral mucositis among patients in study group with the selected demographic variables.

n=30

S.No	Demographic variables	No changes	ositis Mild Oral	s Moderate Oral	sitis severe Oral	Chi square test
1	Age					
	30 – 40 yrs	0	3	1	0	χ^2=12.86
	41 – 50ys	0	5	2	1	df =6,
	51 – 60 yrs	0	4	6	2	Table value=12.59
	>61 yrs	0	0	2	4	
2	Gender					χ^2=1.16 ,
	Male	0	8	6	4	df =2,
	Female	0	4	5	3	Table value =5.99
3	Place of residence					χ^2=2.06 ,
	Rural	0	5	6	5	df =2,
	Urban	0	7	5	3	Table value=5.99
4	Reigion					
	Hindu	0	7	7	4	χ^2=1.93,
	Christian	0	4	4	2	df =4,
	Muslim	0	1	0	1	Table value =9.49
	Others	0	0	0	0	
5	Education					
	Illiterate	0	0	0	0	
	Primary	0	3	3	3	χ^2=2.78,
	Higher secondary	0	4	5	3	df =4,
	Graduates	0	5	3	1	Table value=9.49
6	Occupation					χ^2=3.63
	Govt worker	0	2	1	1	df =6,

	Private worker	0	2	2	2	Table value=12.59
	Self worker	0	3	5	2	
	Unemployment	0	5	3	2	

Table 5.1 shows that in study group, oral mucositis on considering the age, chi square value was 12.86 and the table value at degree of freedom six was 12.59.As per the gender the chi square was 1.16 and the table value at degree of freedom two was 5.99. Considering the place of square value was 2.06 and the table value at degree of freedom two was 5.99. As per religion, the chi residence, chi square was 1.93 and the table value at degree of freedom four was 9.49. Considering the education, chi square value was 2.78 and the table value at degree of freedom four was 9.49. Considering the occupation the chi square was 3.63 and the table value at degree of freedom six was 12.59. Since the chi – square value was lower than the table value there was no association between the oral mucositis with the selected demographic variables like gender,place of residence,religion, eduation and occupation except age.

5.2ASSOCIATION BETWEEN THE POST ASSESSMENT OF ORAL MUCOSITIS AMONG PATIENTS IN STUDY GROUP WITH THE SELECTED CLINICAL VARIABLES.

n=30

S.No	Clinical Variables	No changes	ucositis Mild Oral	tis Moderate Oral	ositis Severe Oral	Chi square test
1	Duration of illness					χ^2=13.04 ,
	0-12 months	0	5	2	1	df =6,
	13- 14months	0	6	3	1	Table value=12.59
	25-36 months	0	1	5	2	
	>37months	0	0	1	3	
2	Number of exposure to radiation therapy					χ^2=11.35,
	0 – 3 times	0	10	3	2	df =4,
	3- 5 times	0	2	7	3	Table value= 9.49
	6 – 8 times	0	0	1	2	
	9 and above	0	0	0	0	
3	Cycle of chemotherapy					χ^2=1.09,
	1 Cycle	0	10	6	3	df =9,
	2 Cycle	0	4	2	1	Table value=16.92
	3 Cycle	0	2	2	0	

Table 5.2 shows that in study group, oral mucositis on considering the duration of illness the chi square value was 13.04 at degree of freedom six was 12.59. As per number of radiation therapy the chi square was 11.35 and the table value at degree of freedom four was 9.49. As per cycle of chemotherapy the chi square was 1.09 and the table value at degree of freedom nine was 16.92. Since the chi – square value was lower than the table value there was association between the oral mucositis with the selected clinical variables like duration of illness and number of exposure to radiation therapy

5.3Association between the post assessment of oral mucositis among patients in control group with the selected demographic variables.

n=30

S.No	Demographic variables	No changes	Mild Oral mucositis	moderate Oral mucositis	Severe Oral mucositis	Chi square test
1	Age					
	30 – 40 yrs	0	2	2	2	χ^2=13.03 df=6, Table value=12.59
	41 – 50ys	0	1	3	2	
	51 – 60 yrs	0	1	6	3	
	>61 yrs	0	0	3	5	
2	Gender					χ^2=1.47 , df =2, Table value=5.99
	Male	0	3	6	7	
	Female	0	1	8	5	
3	Place of residence					χ^2=1.93 df =2, Table value= 5.99
	Rural	0	1	11	6	
	Urban	0	3	3	6	
4	Reigion					
	Hindu	0	2	8	6	χ^2=1.64 df =4, Table value=9.49
	Christian	0	2	5	5	
	Muslim	0	0	1	1	
	Others	0	0	0	0	
5	Education					
	Illiterate	0	0	0	0	χ^2=3.09, df =4, Table value= 9.49
	Primary	0	0	4	3	
	Higher secondary	0	2	6	5	
	Graduates	0	2	4	4	
6	Occupation					
	Govt worker	0	0	2	1	χ^2=2.79, df =6, Table value=12.59
	Private worker	0	2	3	4	
	Self worker	0	1	6	4	
	Unemployment	0	1	3	3	

Table 5.3 shows that in control group, patients with oral mucositis on considering the age, chi square value was 13.03and the table value at degree of freedom six was 12.59.As per the gender the chi square was 1.47 and the table value at degree of freedom two was 5.99. Considering the place of residence, chi square value was 1.93 and the table value at degree of freedom two was 5.99. As per

religion, the chi square was 1.64 and the table value at degree of freedom four was 9.49. Considering the education, chi square value was 3.09 and the table value at degree of freedom four was 9.49. Considering the occupation the chi square was 2.79 and the table value at degree of freedom six was 12.59. Since the chi – square value was lower than the table value there was no association between the oral mucositis with the selected clinical variables like gender, place of residence, religion, eduation and occupation except age.

5.4Association between the post assessment of oral mucositis among patients in control group with the selected clinical variables

n=30

S.No	Clinical variables	No changes	Mild Oral mucositis	Moderate Oral positis	Severe Oral ucositis	Chi square test
1	Duration of illness					
	0-12 months	0	5	2	1	χ^2=12.83 , df =6, Table value=12.59
	13- 14months	0	6	3	1	
	25-36 months	0	1	5	2	
	>37months	0	0	1	3	
2	Number of radiation therapy					
	0 – 3 times	0	10	3	2	χ^2=12.04, df =4, Table value= 9.49
	3- 5 times	0	2	7	3	
	6 – 8 times	0	0	1	2	
	9 and above	0	0	0	0	
3	Cycle of chemotherapy					
	1 cycle	0	10	2	1	χ^2=12.04, df =9, Table value=16.9
	2 cycle	0	5	5	2	
	3 cycle	0	2	1	1	

Table 5.4shows that in study group, patients with oral mucositis on considering the duration of illness the chi square value was 12.83 at degree of freedom six was 12.59. As per number of exposure to radiation therapy the chi square value was 12.04 at degree of freedom four was 9.49 As per cycle of chemotherapy the chi square was 2.45 and the table value at degree of freedom nine was 16.92.Since the chi – square value was lower than the table value there was association between the oral mucositis with the selected demographic variables like duration of illness and number of exposure to radiation therapy except cycle of chemotherapy.

CHAPTER V

DISCUSSION

This study was done to evaluate the effectiveness of natural honey application among patients undergoing radiation therapy with or without chemotherapy at selected Hospital at Kanyakumari District.

Distribution of demographic variables according to their demographic and clinical variables

The demographic variables in study group with expect to age groups were 12(40.0%) belongs to the age group between 51-60 years, 4(13.33%) belong to the age group between 30-40 years. Regarding gender 18 (60%) were males, 12(40%) were females. Regarding the place of residence16 (53.3%) belongs to the rural areas, 14(46.67%) belongs to the urban areas. Regarding the religion 18 (60%) belongs to Hindu religion, 2(6.67%) belong to Muslim. Marital status 30 (100%) were married. As per educational status 12(40%) completed primary and higher secondary education. As per occupation 10(33.3%) were un employees and self-worker, 4(13.33%) were Government worker. With regard to the dietary pattern 30(100%) were non-vegetarian. As per duration of illness 10(33.33%) were with a period of 13-24 months and 4(13.33%) were more than 37 months. As per number of exposure to radiation therapy 12(40%) of them had 3-5 times of exposure to radiation therapy.

In control group 10(33.33%) belong to the age group between 51-60 years, 20 (20%) belong to the age group between 31-40 years and 41-50years. Regarding gender 16(53.33%) were males,14(46.67%) were females. Regarding the place of residence 18(60%) belong to the rural areas,12(40%) belong to the urban areas . Regarding the religion 16 (53.33%) belong to Hindu religion, 2(6.67%) belongs to Muslim. Marital status 30 (100%) were married. As per educational status 14 (46.67%) completed primary education, 6(20%) completed graduation. As per occupation 11(36.67%) were self-worker, 3(10%) were Government worker. With regard to the dietary pattern 30 (100%) were non -vegetarian. As per duration of illness13 (43.33%) had 13-24 months of duration, 2 (6.66%) had more than 37 months of duration. As per number of exposure to radiation therapy 13(43.33%) had radiation 0-2 times and 5(16.67%) of them had 6-8 times of exposure to radiation therapy.

The first objective is to assess the effectiveness of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group and control group

In study group, during pre-assessment, 11(36.67%) had moderate oral mucositis and 19(63.33%) had severe oral mucositis. In control group, 12(40%) had moderate level of oral mucositis, 18(60%) had severe level of oral mucositis.

During post assessment, in study group, 26(87%) had moderate oral mucositis and 4(13.33%) had severe oral mucositis. In control group none of them had no and mild level of oral mucositis, 27(90%) had moderate oral mucositis, 3(10%) had severe oral mucositis. Hence H_1 is accepted

Based on the widenbach's model the second step was demonstrating the natural honey application. Here the researcher gave natural honey application to study group. Then compared the pre assessment and post assessment grades of oral mucositis among patients undergoing with or without chemotherapy in study group and control group. Based on the calculation the result showed that study group experienced reduce in level of oral mucositis than control group.

The second objective of the study is to evaluate the effectiveness of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group and control group.

In study group the calculated't' value for the pre assessment and post assessment level of oral mucositis was 2.042 which was higher than the corresponding table value at 0.05 significant level .So there was significant difference between the pre assessment and post assessment score in study group.

This was supported by a study conducted by **Ana Carolina** (2004) to determine the effect of natural honey application on oral mucositis . The research design was a clinical trial. The subjects of this experiment were radiation therapy patients. To evaluate the effect of natural honey application the oral mucositis was measured by WHO oral mucositis grading scale and oral mucositis scoring were obtained. The data were analyzed by repeated measures of ANOVA, ANCOVA, CHI SQUARE TEST, and multiple response analysis via SPSS program. The WHO oral mucositis grading

scale scale was significantly low in the study group on 10 th and 14th radiation therapy(p=0.009 ,p=0.003),respectively. Most observed few (5 -10 bacteria per field) bacteria in the culture of oral mucositis .These findings indicate that the natural honey application for oral mucositis could be effective in reducing of mucositis.

Similarly in study group the calculated‘t’ value for the pre assessment and post assessment level of oral mucositis was 9.05. The corresponding table value was less than the calculated value at 0.05 significant level. So there was significant difference between the pre and post assessment scores in control group. Hence H_2 hypothesis is accepted

This result was supported by a study conducted by **Frank Man (2009)** to evaluate the effect of honey on oral mucositis . True Experimental design was used.The radiating patients with oral mucositis were selected for this study. WHO oral mucositis grading scale was used to assess the oral mucositis healing .The WHO oral mucositis grading scale was significantly low in the study group on 21st day and no wound healing was identified. These findings indicate that is also effective in reducing the oral mucositis.

Based on the theory third step was explaining the need for natural honey application was met. Here the study group had reduction in oral mucositis. In control group no reduction in the oral mucositis.

The third objective is to determine the association between the post assessment level of oral mucositis among patients undergoing radiation therapy with or without chemotherapy with their selected demographic and clinical variables in study and control group.

There is association ($p<0.05$) between the post assessment level of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group and control group with their selected demographic and clinical variables such as age, duration of illness and number of exposure to radiation therapy at $p<.05$ level. Hence H_3 hypothesis is accepted.

This result was supported by a study conducted by **Dimitrov a, Tsenov D,Ganeva G (2004)** to look for the most probable causes of disturbed healing of oral mucositis .The study is prospective and includes 33patients were 0-2number of

exposure to radiation therapy ‘ The cases are divided into two groups : The first group includes 12 patients with reduced oral mucositis, the second group of 21 cases with soreness and erythema ,8 with superficial wound in oral. For a period of 5 years the mean rate of entirely open wound is1.07% . According to the result the process of oral mucositis is not influenced by age of the patients , type of diet ,duration of illness.

There was a significant difference between the post assessment level of oral mucositis in study group and control group .The study represents the natural honey application is efficient with the ‘t’ value level of 2.36 at 0.05 level of significance. This study statistically proved the natural honey application is effective on oral mucositis among patient undergoing radiation therapy with or without chemotherapy.

CHAPTER – VI

SUMMARY, CONCLUSION, LIMITATIONS, NURSING IMPLICATION AND RECOMMENDATIONS

This chapter deals with the summary of the study, conclusion, nursing implications, limitations and recommendations of the study.

SUMMARY

Quantitative approach with quasi experimental pre assessment and post assessment control group research design was used to determine the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy. The conceptual framework for the study was based on modified widenbach's prescriptive helping art of clinical nursing model. The tool used in this study was the WHO oral mucositis grading scale. Purposive sampling technique was used to select the samples and data was collected from the participants in study group and control group. In study group, after the pre assessment to the patients, The researcher arrange the arrange the articles with a tray containing natural honey 10 m.l, bowl, gauze pieces ,artery forceps .Assemble the articles nearer to the bed side . Explain the procedure to the patient. The researcher makes the patient to sit in comfortable position. Wash the hands .Wear thegloves, then apply the natural honey over the mucositis area with the help of artery forceps and gauze for 15 minutes. The researcher makes the patient back in comfortable position. In control group, the samples were proceeded with routine care in the hospital. In study group the selected patients were assessed on the 7^{th} day of intervention and control group also the selected patient's were assessed on the 7^{th} day of intervention. The data was collected and analysed using descriptive and inferential statistics. The level of significance was assessed by $p<0.05$ to test the hypothesis.

FINDINGS

The major findings of that study was summarised as follows, the demographic variables in study group indicates that 12(40.0%) belongs to the age group between 51-60 years, 4(13.33%) belong to the age group between 30-40 years. Regarding gender 18 (60%) were males, 12(40%) were females. Regarding the place of residence16 (53.3%) belongs to the rural areas, 14(46.67%) belong to the urban areas. Regarding the religion 18 (60%) belong to Hindu religion, 2(6.67%) belong to muslim. Marital status 30 (100%) were to married. As per educational status 12(40%)completed primary and higher secondary education. As per occupation

10(33.3%) were unemployees and self worker, 4(13.33%) were Government worker . With regard to the dietary pattern 30(100%) were non-vegetarian. As per duration of illness10(33.33%) had duration for 13-24 months and 4(13.33) had for more than 37 months. As per number of radiation therapy 12(40%) of them had to 0-2 and 3-5 times of radiation therapy.

The demographic variables in control group were with 10(33.33%) of them in the age group between 51-60 years, 20 (20%) in the age group between 31-40 years and 41-50years. Regarding gender 16(53.33%) were males,14(46.67%) were females. Regarding the place of residence 18(60%) belongs to the rural areas,12(40%) belongs to the urban areas . Regarding the religion 16 (53.33%) belongs to Hindu religion, 2(6.67%) belongs to muslim. Marital status 30 (100%) were married. As per educational status 14 (46.67%)completed primary , 6(20%) completed graduation. As per occupation 11(36.67%) were self worker, 3(10%) were Government worker. With regard to the dietary pattern 30 (100%) were non -vegetarian. As per duration of illness13(43.33%) had 13-24 months of duration, 2 (6.66%) had more than 37 months of duration. As per number of radiation therapy 13(43.33%) of them had 0-2 times of exposure to radiation therapy,5(16.67%) of them had to 6-8 times of exposure to radiation therapy.

During pre assessment, in study group , 11(36.67%) had moderate level of oral mucositis and 19(63.33%) had severe oral mucositis. In control group none of them had no and mild level of oral mucositis, 12(40%) had moderate level of oral mucositis, 18(60%) had severe level of oral mucositis.

During post assessment, in study group , 26(87%) had moderate oral mucositis and 4(13.33%) had severe oral mucositis. In control group none of them had no and mild level of oral mucositis, 27(90%) had moderate oral mucositis, 3(10%) had severe oral mucositis.

The mean score on level of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in study group was 2.69 in pre assessment and 0.49 in post assessment. The estimated paired‘t’ value was 2.042**,** so there was difference in the pre assessment and post assessment scores of oral mucositis . Similarly in control group the mean score on level of oral mucositis

among patients undergoing radiation therapy with or without chemotherapy was 2.20 in pre assessment and 0.49 in post assessment. . The estimated paired‘t’ value was 2.043**,** so there was differences in the pre assessment and post assessment scores of oral mucositis .

In post assessment, mean score level of oral mucositis of the study group was 2.042 and the mean score of the control group was 2.042. There was significant difference between the study group and control group which was computed through independent ‘t’ test value was 2.36.The score represents the effectiveness of natural honey application is effectiveness for oral mucositis.

CONCLUSION

The study was effectiveness of natural honey on oral mucositis among patients with radiation therapy with or without chemotherapy selected hospital at Kanyakumari district.

The findings reveals that, in study group during pre assessment, among 30 samples. The demographic variables in control group 10(33.33%) of them belongs to the age group between 51-60 years, 16(53.33%) of them were males, 18(60%)of them were belongs to rural areas , 16 (53.33%) of them were Hindu religion, Marital status 30 (100%) were married, 14 (46.67%) of them were primary education , 11(36.67%) of were self worker, 30 (100%) were non -vegetarian. 13(43.33%) had 13-24 months duration of illness, 13(43.33%) belongs to 0-2 times of radiation therapy,5(16.67%) had undergone the 6-8 times of radiation therapy.

During pre assessment, in study group ,26(87%) had moderate oral mucositis and 4(13.33%) had severe oral mucositis. In control group, 27(90%) had moderate oral mucositis, 3(10%) had severe oral mucositis. There was no significant difference in the pre assessment and post assessment level of oral mucositis in study and control group at 0.05 significant.

There was a significant difference between the post assessment level of oral mucositis in study group and control group .The study represents the natural honey application is efficient with the ‘t’ value level of 2.36 at 0.05 significant .

From the result of the study, it was concluded that most of the patients undergoing radiation therapy with or without chemotherapy had oral mucositis. The remedies were needed for oral mucositis . Natural honey application to the patients undergoing radiation therapy with or without chemotherapy was effective in reducing oral mucositis. Therefore the investigator felt that more importance should be given for natural honey application to reduce level of oral mucositis in patients undergoing radiation therapy with or without chemotherapy.

NURSING IMPLICATIONS

The researcher has derived the following implications from the study results which are of vital concern to the field of nursing service, nursing administration, nursing education and research.

Implication for nursing practice

Nurses should develop indepth knowledge about the side effects of radiation therapy. Nurses should be knowledgeable regarding the benefits of complementary therapy including natural honey application in reducing level of oral mucositis in patients undergoing radiation therapy with or without chemotherapy, which should be practiced in the hospital or community.

Nurses should educate and encourage patients undergoing radiation therapy to use natural honey application during radiation therapy.

Nurses should incorporate health and complementary treatment plans during their service whenever it is possible.

Implication for nursing education

Nurse educators need to be equipped with indepth knowledge and skill regarding natural honey application.

Nursing students should receive adequate training regarding the application of natural honey application, physiology and the specific health benefits of regular practicing of the natural honey application technique.

Nurses should conduct workshops or conferences for students regarding the benefit of natural honey application in a day today nursing practice and strengthen the curriculum for nurses to excel them in knowledge and skill in areas of various modalities.

Implication for nursing administration

Nurses should assist in implementing public health awareness campaigns aimed at reducing oral mucositis.

Nurses should provide knowledge, resources and leadership for establishing public health policies that focus on natural honey application for oral mucositis among patients undergoing radiation therapy with or without chemotherapy.

Public information programs should be designed by nurses to encourage natural honey application therapy for patients undergoing radiation therapy with or without chemotherapy.

Implication for nursing research

Nursing research is to be done to find out the various innovative method to reduce oral mucositis.

The finding of the study would help to expand the scientific body of professional knowledge upon which the research can be conducted.

Large scale study should be conducted on natural honey application on oral mucositis and disseminate the finding of research through conferences, seminars and publishing in nursing journals.

RECOMMENDATIONS

The following studies can be undertaken to strengthen natural honey as a good remedy for reducing the oral mucositis among patients undergoing radiation therapy with or without chemotherapy.

- A similar study can be conducted with increased in the sample size.
- A similar study can be conducted in long time period with various parameters.

LIMITATIONS

Since there were very few studies done on the effectiveness of honey to reducing oral mucositis , the researcher had lot of difficulty in collecting the study materials for the review.

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ANNEXURE –I

St. XAVIER'S CATHOLIC COLLEGE OF NURSING

Chunkankadai, Nagercoil,
Kanyakumari District,
Tamil Nadu - 629 003.

Tel : College : 04651 - 231740
Cell : 9843037884
Fax : 04651 - 230914
E-mail : xaviers_nursing@yahoo.com
rcmaevancy@yahoo.com
Website : www.xaviersnsg.edu.in

Dr. A. REENA EVENCY, M.Sc. (N)., Ph.D.,
Principal

To

Medical Superindent ,

C.S.I Medical Mission Hospital,

Neyyoor.

Respected sir,

MS.Jasmin Joy.G is a student of M.sc. Nursing program in our college from Medical and Surgical Nursing Department. She is conducting study on" **A study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital ,kanyakumari district."**

This is the research project to be submitted to the Dr.M.G.R.Medical University in partial fulfillment of university requirement for the award of M.Sc. Nursing degree and will be beneficial in understanding and improving the health of the patients with oral mucositis undergoing radiation therapy and chemotherapy.

As a part of her study she needs to observe the improvement of patients with oral mucositis in your hospital. So permission may kindly be granted to her to conduct the study in your esteemed hospital .she will abide by the rules and regulations of your hospital.

Thanking you.

Yours faithfully.

ANNEXURE-II

KANYAKUMARI MEDICAL MISSION C.S.I.
INTERNATIONAL CANCER CENTRE, NEYYOOR

Pro. Dr. V.G. SUDHAKARAN, M.D.
Consultant Radiation Oncologist &
Head of the Dept. Radiation Oncology
E-mail : drvgsudhakaran@gmail.com

NEYYOOR - 629 802
KANYAKUMARI DISTRICT
TAMIL NADU, S. INDIA
Phone : 04651-222334
Mob : 09789236999

Date : 01.07.2015

To

The Principal,
St.Xavier's Catholic College of Nursing,
Chunkankadai,
Nagercoil – 629 003.
K.K. Dist.

Sir,

Sub: Permission for M.Sc., Nursing project – Regarding

We are glad to inform that we approved permission to your college student **MS.Jasmin Joy G,** to undergo project on "**A study to evaluate the effectiveness of natural honey on oral mucositis among patients undergoing radiation therapy with or without chemotherapy"** in our hospital from 01-07-2015 to 31-07-2015 . We trust that your student will abide our hospital rules and regulations.

Thanking you,

Dr. V.G. SUDHAKARAN,
B.Sc., M.B.B.S., M.D., DMRT.,
Reg. No. [illegible]
Head of Department
INTERNATIONAL CA
NEYYOOR

ANNEXURE- III

LETTER SEEKING EXPERTS OPINION FOR THE VALIDITY OF THE TOOL

St. XAVIER'S CATHOLIC COLLEGE OF NURSING

Chunkankadai, Nagercoil,
Kanyakumari District,
Tamilnadu - 629 003.

Tel College : (04651 - 251540)
Cell : 9840307884
Fax : 04651 - 230914
E-mail : xaviers_nursing@yahoo.com
Website : www.xaviersnsg.edu.in

B.Sc. (N) Approved by Govt. of Tamilnadu G.O. (Ms) No. 170/2008 Approved by INC, New Delhi 16-29/2011-INC/2008 Registered under T.N. Nursing Council Ref. No. 3436/C/2008 Affiliated to the T.N. Dr. M.G.R. Medl. Uni., Chennai Affln. No.3504706
P.B.B.Sc(N) G.O. (Ms) No. 170/2008 16-29/4284-INC/2010 Ref. No. 3419/NC/2009 Affln. No.3647269
M.Sc. (N) 16-29/7573-INC/2011 Ref. No. 4478/NC/2011 Affln. No.3728110

To

Respected Sir/ Madam,

Sub: Requisition to expert opinion and suggestion for the content validity.

I Ms.Jasmin Joy.G, M.Sc. Nursing II year student of St.Xavier's Catholic College Of Nursing, Chunkankadai, have selected the following topic, **"A study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital ,Kanyakumari district."** for my dissertation to be submitted to Tamilnadu Dr. M.G.R. Medical University in the partial fulfillment of the requirement for award of Master of science in Nursing.

I request you to go through the items and give your valuable suggestions and opinions to develop the content validity of the tool. Kindly suggest modifications, addition and deletions if any in the remarks column.

Thanking You,

Place: Chunkankadai.
Date: 25-05-2015

Yours sincerely,
Jasmin Joy.G

ENLOSURE:

1. Problem statement, objectives, and hypothesis of the study.
2. Demographic profile.
3. WHO Oral Mucositis Grading Scale.
4. Evaluation Performa.

ANNEXURE - IV

EVALUATION CRITERIA CHECKLIST FOR VALIDATION

Instructions:

The expert is requested to go through the following criteria for evaluation. Three columns are given for responses and a column for remarks. Kindly please tick mark (✓) in the appropriate columns and give remarks. Interpretation column:

Column I – meets the criteria.

Column II - Partially meets the criteria.

Column III – does not meet the criteria.

S.No	CRITERIA	1	2	3	REMARKS
1	Scoring -adequacy. -clarity. -simplicity.				
2	Content -logical sequence. -adequacy. -relevance.				
3	Language -Appropriate. -clarity. -simplicity.				
4	Practicability -easy to score. -precise. -utility.				

Signature: Any other suggestion:

Name:

Designation:

Address:

CRITERIA CHECK LIST FOR VALIDATION OF THE TOOL

Instruction:

Kindly give your suggestions regarding the accuracy, relevance and appropriateness of the content. Kindly (✓) against specific columns.

PART-I

Validation of Demographic variables.

Item	Very relevant	Relevant	Need for modification	Not relevant	Remarks
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					

PART-II

WHO Oral Mucositis Grading scale scoring.

Item	Very relevant	Relevant	Need for modification	Not relevant	Remarks
1					
2					
3					
4					
5					
6					
7					
8					

PART-III

Validation of WHO Oral Mucositis Grading Scale.

Item	Very relevant	Relevant	Need for modification	Not relevant	Remarks
1					
2					
3					
4					
5					

ANNEXURE - V

LIST OF EXPERTS WHO VALIDATED THE TOOL

1. Dr.V.G.Sudakaran, MD.DMRT,

   Head of the Department of Radiation Oncology

   International Cancer Centre,

   Neyyoor, Kanyakumari District,

Pin code-629802

2. Dr. A.Jeba priya, M.B.B.S.,DMRT.

Consultant Oncologist,

Holy Cross Hospital, Vettoorimadam, Nagercoil ,

Kanyakumari District.

3. Dr.Sharmila, M.Sc(N),Ph.D.

professor,

Christian College of Nursing, Neyyoor,

Kanyakumari District.

4 .Mrs. Josephine sudha., M.Sc (N).,

Reader,

p.s college of nursing,

Thalakkulam.

5. Mrs.Sheeba, M.Sc.(N),

Reader,

Christian College of Nursing, Neyyoor,

Kanyakumari District.

ANNEXURE – VI

Dr.Y.R.MANEKSHAH, BSMS,MD(siddha)
Specialist Infertility
No.31, Theresa Heaven, Thiruvalluvar Nagar, 2nd Street,
Alandur, Chennai - 16.Tamil Nadu.

TO WHOM SO EVER IT MAY CONCERN

This to certify that **MS.Jasmin Joy**.G , M.sc Nursing II year student of St. Xavier's Catholic College of Nursing ,Chunkankadai will be conducted a study on **" a study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital ,Kanyakumari district"** ,in which she is using honey from house – roofs, and the honey is good for oral mucositis

29/6/2015

ராஜ வைத்தியசாலை
Raja Vaidyasalai
K.P. Road, Mathias Nagar,
Nagercoil - 629 001.
Ph : 9487371170

Dr. Y.R. MANEKSHAH, M.D(Sidd...
Regn. No : 260
Consultant Physician (Siddha)
Raja Vaidyasalai, 189-C, K.P. Road,
Mathias Nagar, Nagercoil-629 001.

Raja Vaidyasalai
No.189-c, K.P.Road, Mathias Nagar, Nagercoil - 629 001.Tamil Nadu.
Mobile : +91 9487371170
E-mail : drmanekshahmd@gmail.com | www.herbalinfertility.com

ANNEXURE: VII

TOOL FOR DATA COLLECTION

The tool will be used in the study consist of two parts

PART: A

Demographic data consists of age, gender, place of residence, religion, marital status, education, occupation, type of diet, duration of illness, number of exposure to radiation therapy, cycle of chemotherapy.

DEMOGRAPHIC AND CLINICAL VARIABLES

1) Age
   a) 30-40 yrs
   b) 41-50 yrs
   c) 51-60 yrs
   d) Above 60 yrs

2) Gender
   a) Male
   b) Female

3) Place of residence
   a) rural
   b) urban

4) Religion
   a) Hindu
   b) Christian
   c) Muslim
   d) Others

5) Marital status
   a) Married
   b) Unmarried
   c) Widow or widower
   d) Separated

6) Education
   a) Illiterate
   b) Primary
   c) Higher secondary
   d) Graduates

7) Occupation

a) Govt-worker
b) Private worker
c) Self worker
d) Unemployment

8) Type of diet

a) Vegetarian
b) Non vegetarian

9) Duration of illness

a) 0-12 months
b) 13-24 months
c) 25-36 months
d) More than 37 months

10) Number of exposure to radiation therapy

a) -2 times
b) 3 - 5 times
c) 6 -8 times
d) 9 and above

11) Cycle of chemotherapy

a) 1 cycle
b) 2 cycle
c) 3 cycle

PART B

WHO Oral Mucositis Grading Scale

Grade 0 (No Changes)	none

Grade 1 (Mild Oral Mucositis)	Soreness + erythema
Grade 2 (Moderate Oral Mucositis)	Erythema , ulcers; patients can swallow solid diet
Grade 3 (Severe Oral Mucositis)	Ulcers, extensive erythema; patients cannot swallow solid diet
Grade 4 (Life Threatening)	Mucositis to the extent that alimentation is not possible

Interpretation :

0 : No Changes

1: Mild Oral Mucositis

2: Moderate Oral Mucositis

3: Severe Oral Mucositis

4: Life-Threatening

ANNEXURE - VIII

DATA COLLECTION PERIOD, NUMBER OF SAMPLE AND METHOD OF SAMPLE SELECTION

S.no	Date	Number of samples		Method of sample selection
		Study group	control group	
1	01-07-2015	03		Purposive sampling technique was used
2	03-07-2015	03		
3	05-07-2015	03		
4	06-07-2015	02		
5	08-07-2015	02		
6	09-07-2015	03		
7	10-07-2015	02		
8	11-07-2015	05		
9	12-07-2015	03		
10	13-07-2015	01		
11	14-07-2015	02		
12	15-07-2015	03		
13	16-07-2015		03	
14	17-07-2015		03	
15	18-07-2015		02	
16	19-07-2015		03	
17	20-07-2015		02	
18	22-07-2015		04	
19	23-07-2015		02	
20	24-07-2015		03	
21	25-07-2015		02	
22	26-07-2015		01	
23	27-07-2015		02	
24	29-07-2015		03	

ANNEXURE- IX

CERTIFICATE STATISTICAL ANALYSIS AND INTERPRETATION

CERTIFICATE OF STATISTICAL ANALYSIS

TO WHOM SO EVER IT MAY CONCERN

Certified the dissertation paper titled **"A study to evaluate the effectiveness of natural honey application on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital at Kanyakumari district"** done by Ms.Jasmin Joy.G has been checked for the accuracy in statistical analysis and interpretation and was appropriate for the purpose.

Signature 5/2/16
Dr. G. IMMANUEL, Ph.D.
Assistant Professor
Centre for Marine Sciences & Technol
Manonmaniam Sundaranar University
Rajakkamangalam-629 502
K.K. District, South India

ANNEXURE - X

CERTIFICATE OF ENGLISH EDITING

CERFIFICATE OF ENGLISH EDITING

TO WHOM SO EVER IT MAY CONCERN

Certified the dissertation paper titled "**A study to evaluate the effectiveness of natural honey on oral mucositis among patients undergoing radiation therapy with or without chemotherapy in selected hospital at kanyakumari district**" by Jasmin Joy.G has been Checked for accuracy and correctness of English language usage and that the language in the tool is lucid, unambiguous free of grammatical and spelling errors and appropriate for the purpose.

signature

Correspondent
St. Mary's School (CBSE)
Amanattantheri, Enayam,
K. Dist. Tamil Nadu - 629193

ANNEXURE-XII

PROCEDURE FOR NATURAL HONEY APPLICATION

INTRODUCTION:

Good morning, I am student of St. Xavier's Catholic College of Nursing, individuals with oral mucositis due to the radiation therapy and chemotherapy. So natural honey application is the best way to reduce the oral mucositis .

BENEFITS:

1. Using honey to manage wounds impaired by radiotherapy.
2. Antitumor properties of honey.
3. Anti-proliferative effects of honey.
4. To reduce the pain odour and to kill any remaining active spores.
5. To give moisture effect on oral mucositis.

Procedure of natural honey application:

The researcher assemble the articles with a tray containing natural honey 10 m.l, bowl, gauze pieces, artery forceps. Assemble the articles nearer to the bed side. Explain the procedure to the patient. The researcher makes the patient to sit in comfortable position. Wash the hands .Wear the Gloves, and then apply the natural honey over the mucositis area with the help of artery forceps and gauze for 15 minutes. The researcher makes the patient back in comfortable position.

ANNEXURE- XII

FORMULAS USED FOR DATA ANALYSIS

DESCRIPTIVE STATISTICS

Mean

$$\acute{x}=\frac{\sum x}{N}$$

Standard deviation

$$s=\sqrt{\frac{\sum\left(x-\acute{x}\right)^2}{n-1}}$$

INFERENTIAL STATISTICS

Independent't' test

$$t=\frac{\left|x_1-x_2\right|}{\sqrt{\frac{{s_1}^2}{n_1}+\frac{{s_2}^2}{n_2}}}$$

$$s=\sqrt{\frac{\left(n_1-1\right){s_1}^2+\left(n_2-1\right){s_2}^2}{n_1+n_2-2}}$$

Paired't' test

$$t=\frac{\acute{d}\sqrt{n}}{s}$$

$$s=\sqrt{\frac{\sum\left(d-\acute{d}\right)^2}{n-1}}$$

Chi-Square test

$$x^2=\sum\frac{\left(o-e\right)^2}{e}$$

ANNEXURE XIII

PHOTOGRAPHS